HTA Austria
Austrian Institute for
Health Technology Assessment
GmbH

Transarterial periarticular embolisation (TAPE) for knee and shoulder osteoarthritis

Systematic Review

AIHTA Decision Support Document: 148 | ISSN-online: 1998-0469

HTA Austria
Austrian Institute for
Health Technology Assessment
GmbH

Transarterial periarticular embolisation (TAPE) for knee and shoulder osteoarthritis

Systematic Review

Vienna, February 2026

Project Team

Project leader: Julia Kern, MSc

Authors: Dr.in scient.med Cornelia Krenn, BSc MSc
Univ. Ass. Mag. rer. nat. Thomas Semlitsch
Dr.in rer.hum.biol. Denise Wilfling, BSc MSc
Institute of General Practice and Evidence-Based Health Services Research, Medical University of Graz

Project Support

Systematic literature search: Tarquin Mittermayr, MA; AIHTA

External Review: Priv. Doz. Dr. Roman Radl, MBA

Internal Review: Julia Kern, MSc; AIHTA, Gregor Goetz, Dr. PH MSSc MPH; AIHTA

Correspondence: Julia Kern; AIHTA, Julia.Kern@aihta.at

This report should be referenced as follows:

Krenn C, Semlitsch T, Wilfling D. Transarterial periarticular embolisation (TAPE) for knee and shoulder osteoarthritis. AIHTA Decision Support Documents No. 148; 2026. Vienna: Austrian Institute for Health Technology Assessment GmbH.

Conflict of interest

All authors and the reviewers involved in the production of this report have declared they have no conflicts of interest in relation to the technology assessed according to the Uniform Requirements of Manuscripts Statement of Medical Journal Editors (www.icmje.org).

Disclaimer

The external reviewers did not co-author the scientific report and do not necessarily all agree with its content. Only the AIHTA is responsible for errors or omissions that could persist. The final version and the policy recommendations are under the full responsibility of the AIHTA.

The HTA Core Model®, developed within EUnetHTA (www.eunethta.eu), has been utilised when producing the contents and/or structure of this work. The following version of the Model was used: [HTA Core Model®, Version 4.2]. Use of the HTA Core Model does not guarantee the accuracy, completeness, quality or usefulness of any information or service produced or provided by using the Model.

Commissioned by the Austrian Ministry of Health, this report systematically assessed the intervention described herein as decision support for the inclusion in the catalogue of benefits.

IMPRINT

Publisher:
HTA Austria – Austrian Institute for Health Technology Assessment GmbH
Josefstädter Str. 39 | 1080 Vienna – Austria
https://www.aihta.at/

Responsible for content:
Dr.in rer. soc. oec. Ingrid Zechmeister-Koss, managing director

AIHTA Decision Support Documents do not appear on a regular basis and serve to publicize the research results of the Austrian Institute for Health Technology Assessment.

AIHTA Decision Support Documents are only available to the public via the Internet at http://eprints.aihta.at/view/types/hta_report.html.

AIHTA Decision Support Documents No.: 148

ISSN online 1998-0469

Content

List of figures

List of tables

List of abbreviations

ADL ..... Activities of daily living
AE ..... Adverse event
ASES ..... American Shoulder and Elbow Surgeons Score
CI ..... Confidence interval
CT ..... Computed tomography
DGOU ..... Deutsche Gesellschaft für Orthopädie und Unfallchirurgie
DSA ..... Digital subtraction angiography
EQ-5D-5L ..... European Quality of Life 5 Dimensions 5 Level Version
EUnetHTA ... European Network for Health Technology Assessment
FDA ..... Food and Drug Administration
GAE ..... Genicular artery embolisation
GRADE ..... Grading of Recommendations Assessment, Development and Evaluation
HADS ..... Hospital Anxiety and Depression Scale
HRQoL ..... Health-related quality of life
ICD-11 ..... International Classification of Diseases, Eleventh Revision
ICOAP ..... Intermittent and Constant Osteoarthritis Pain
INAHTA ..... International HTA Database
KOOS ..... Knee Injury and Osteoarthriti Outcome Score
MRI ..... Magnetic resonance imaging
NA ..... Not applicable
NI ..... No information
NICE ..... National Institute for Health and Care Excellence
NR ..... Not reported
NS ..... Not significant
NSAID ..... Non-steroidal anti-inflammatory drug
OA ..... Osteoarthritis
OSF ..... Open Science Framework
RCT ..... Randomised controlled trial
RoB ..... Risk of Bias
SAE ..... Serious adverse event
SPADI ..... Shoulder Pain and Disability Index
TAE ..... Transcatheter arterial embolisation
TAPE ..... Transarterial periarticular embolisation
UCLA ..... University of California-Los Angeles
UK ..... United Kingdom
USA ..... United States of America
VAS ..... Visual analogue scale
WOMAC ..... Western Ontario and McMaster Universities Osteoarthritis Index

Executive Summary

Introduction

Health Problem

Osteoarthritis (OA) is a complex, degenerative joint disease and one of the most prevalent causes of chronic disability due to pain and altered joint function in adults, with the knee being among the most commonly affected joint. OA affects the entire joint, involving cartilage degradation, subchondral bone remodeling, and synovial inflammation. Its aetiology is multifactorial, combining systemic risk factors with local mechanical stress that triggers a low-grade inflammatory process leading to joint destruction. The natural course of OA is characterised by slow, progressive deterioration over many years. Primary symptoms include pain, stiffness, swelling, and limitations in joint function, while the disease burden extends beyond physical manifestations to negatively impact mental health, sleep quality, work productivity, and overall quality of life. Age represents the most significant non-modifiable risk factor, alongside personal factors such as metabolic disorders, obesity, rheumatoid arthritis, high-intensity sports, and occupational physical load, as well as joint-specific factors including trauma, deformities, and localised pathologies.

Description of Technology

Transarterial and periarticular embolisation (TAPE) is a minimally invasive, catheter-based interventional procedure for local pain therapy in OA. The reduction of local hypervascularisation is achieved by super-selective embolisation of periarticular arteries using embolic agents. In TAPE, temporary substances or permanent microspheres are used as embolisation materials, which are directed to the painful joint or tendon site via a catheter through the groin, aiming to reduce immediate and usually longer-lasting pain. TAPE can be applied to various joints. For example, when applied to the knee joint, the procedure is referred to as genicular artery embolisation (GAE), which specifically targets the genicular arteries supplying the periarticual tissue of the knee.

Methods

The aim of this review was to compare the safety and efficacy of TAPE with conservative treatments (physical therapy, exercise, weight management), pharmacological treatment (e.g., NSAIDs, including Cox-2 inhibitors, acetaminophen, steroid injections) or surgical joint replacement in patients with knee or shoulder OA. A systematic literature search for primary studies was conducted in four databases (Medline, Embase, Cochrane Library, INAHTA). To identify ongoing and unpublished studies, an additional search in three clinical trials registries (ClinicalTrials.gov, WHO-ICTRP, and EU Clinical Trials) was conducted. Study selection was conducted independently by two assessors. Data extraction was performed by one assessor and validated by a second. Certainty of evidence was assessed according to the GRADE (Grading of Recommendations Assessment, Development and Evaluation) framework.

Domain effectiveness and safety

The following efficacy outcomes were considered critical to derive a recommendation: Change in pain intensity, change in physical function, change in symptoms, change in concurrent medication intake and treatment, activities of daily living (ADLs), health-related quality of life (HRQoL), psychosocial outcomes (e.g., depression, anxiety, sleep quality), and technical success. Serious adverse events (SAE) and adverse events (AE) were considered critical safety outcomes for decision making.

Results

Available evidence

This review included three randomised controlled trials (RCTs) encompassing a total of 138 patients, each investigating the effectiveness of GAE TAPE in comparison to sham embolisation for symptomatic knee OA. No study could be identified investigating the effectiveness of TAPE in patients with shoulder OA.

Clinical effectiveness and safety

GAE demonstrated statistically significant improvements in pain intensity after one month in comparison to sham embolisation. However, no significant between-group differences regarding pain relief were observed at long-term follow-up (four to twelve months). Physical function improved significantly at four months follow-up. No significant improvements were reported for joint-specific symptoms, ADLs, HRQoL, psychosocial outcomes, or concurrent medication intake and treatment. One RCT reported a 100% technical success rate of the procedure. No SAEs were reported in the included RCTs. AEs were predominantly mild and self-limiting.

Upcoming evidence

A total of 15 ongoing RCTs comparing TAPE with sham treatment (n=12), observation (counselling on conservative management with a referral or prescription for physical therapy; n=1) or standard care (n=2) are listed in the trial registers, with primary endpoints including pain, function, stiffness, ADLs, HRQoL, analgesia usage and safety. The planned study completion dates are between 2026 and 2028. No registered ongoing trials addressing TAPE for shoulder OA could be identified.

Reimbursement

The Austrian hospital benefit catalogue from 2026 does not include TAPE for treatment of knee or shoulder OA. Therefore, it is not fully reimbursed by the Austrian healthcare system.

Discussion and Conclusion

The generalisability of the findings is limited by the small number of available RCTs, limited sample sizes, heterogeneity in embolic agents, varying follow-up time points, and methodological concerns regarding the exclusion of non-responders in one study. The current evidence is inconclusive to indicate an added benefit for TAPE in patients with symptomatic knee OA in routine use or in specific indications. The review highlights the need for further studies investigating TAPE in patients with knee and shoulder OA.

Zusammenfassung

Einleitung

Indikation und therapeutisches Ziel

Osteoarthritis, im deutschsprachigen Raum als Arthrose bezeichnet, ist eine komplexe, degenerative Gelenkerkrankung. Sie ist eine der häufigsten Ursachen für chronische körperliche Beeinträchtigungen bei Erwachsenen, die primär durch Schmerzen und einer veränderten Gelenkfunktion verursacht wird. Während die Erkrankung prinzipiell jedes Gelenk betreffen kann, zählt das Kniegelenk (Gonarthrose) zu den häufigsten betroffenen Lokalisationen. Die Pathophysiologie der Arthrose wird heute als Erkrankung des gesamten Gelenkorgans verstanden. Der Prozess beschränkt sich nicht auf den Abbau des Gelenkknorpels, sondern umfasst auch den Umbau des subchondralen Knochens (Sklerosierung, Zystenbildung, Osteophyten) sowie entzündliche Veränderungen der Synovialis (Synovialmembran). Die Ätiologie ist multifaktoriell: Eine Kombination aus systemischen Risikofaktoren und lokaler mechanischer Belastung triggert einen niedrig-gradigen Entzündungsprozess, der zu einer Gelenkdestruktion führt.

Der natürliche Verlauf ist durch eine langsame, über Jahre fortschreitende Verschlechterung gekennzeichnet. Initiale Symptome sind oft mild und intermittierend, entwickeln sich jedoch zu häufigeren und persistierenden Schmerzen. Zu den klinischen Hauptmanifestationen zählen Belastungs- und Ruheschmerz, morgendliche Steifheit, Schwellneigung und funktionelle Einschränkungen. Die Krankheitslast erstreckt sich weit über die physischen Symptome hinaus und beeinträchtigt signifikant psychosoziale Parameter wie die psychische Gesundheit (z. B. depressive Verstimmungen, Angststörung), die Schlafqualität, die Arbeitsproduktivität und die allgemeine gesundheitsbezogene Lebensqualität.

Das Alter stellt den signifikantesten nicht-modifizierbaren Risikofaktor dar. Darüber hinaus tragen diverse persönliche und gelenkspezifische Faktoren zur Degeneration bei. Zu den persönlichen Risikofaktoren zählen metabolische Erkrankungen (Diabetes mellitus, Gicht), Adipositas, rheumatoide Arthritis sowie Hochleistungssport und schwere berufliche körperliche Belastung. Zu den gelenkspezifischen Faktoren zählen vorangegangene Traumata (Frakturen, Bandverletzungen), angeborene oder erworbene Fehlstellungen sowie lokale Pathologien. Der Schweregrad wird radiologisch (z. B. Kellgren-Lawrence-Score) und klinisch klassifiziert, wobei die Therapieentscheidung primär von der individuellen Symptomlast abhängt.

Beschreibung der Technologie

Die transarterielle periartikuläre Embolisation (TAPE) ist ein minimal-invasives, kathetergestütztes interventionelles Verfahren zur lokalen Schmerztherapie bei Patienten:innen mit Arthrose. TAPE wird insbesondere zur Behandlung der Gonarthrose eingesetzt.

Unter Verwendung der digitalen Subtraktionsangiographie (DSA) erfolgt nach Kontrastmittelgabe zunächst eine Visualisierung der arteriellen Gefäßversorgung des betroffenen Gelenks. Typischerweise findet sich ein hypervaskularisiertes Gewebemuster in den betroffenen Gelenkabschnitten, welches „wolkenartig“ als sog. Blush darstellbar ist und Zonen der Neovaskularisierung entspricht. Unter bildgestützter Kontrolle wird ein Mikrokatheter superselektiv in die betroffenen periartikulären Gefäße vorgeführt. Im Anschluss erfolgt die Injektion eines Embolisats zur Ausschaltung des pathologischen Blush. Als Embolisationsmaterialien kommen entweder temporäre Substanzen (z. B. Imipenem/Cilastatin) oder permanente Mikrosphären zum Einsatz, die einen vorübergehenden Verschluss der schmerzhaften Gelenkarterien bewirken. Die Embolisation führt zu einem temporären oder dauerhaften Verschluss der periartikulären Gefäßversorgung, wodurch die lokale Hypervaskularisation sowie die entzündungsbedingte Hyperperfusion vermindert werden. TAPE kann an verschiedenen Gelenken angewendet werden. Bei der Anwendung am Kniegelenk wird das Verfahren als genikuläre Arterienembolisation (GAE) bezeichnet, die spezifisch auf die Genikulararterien abzielen, welche das periartikuläre Gewebe des Knies versorgen.

Methoden

Ziel des vorliegenden Berichts war es, die Wirksamkeit und Sicherheit von TAPE im Vergleich zu konservativen Standardtherapien (z. B. Physiotherapie, Bewegung, Gewichtsreduktion), medikamentöse Therapien (z. B. NSAIDs, einschließlich Cox-2-Hemmer, Paracetamol, Steroidinjektionen) oder chirurgischen Gelenkersatz bei Patient:innen mit Knie- oder Schulterarthrose zu vergleichen.

Im November 2025 wurde eine systematische Literaturrecherche in vier bibliografischen Datenbanken (MEDLINE, Embase, Cochrane Library, INAHTA) nach Primärstudien in englischer oder deutscher Sprache durchgeführt. Zusätlich erfolgte eine Suche nach laufenden Studien im Dezember 2025 in drei klinischen Studienregistern (ClinicalTrials.gov, WHO-ICTRP, EU Clinical Trials). Die Studien wurden von zwei Personen unabhängig voneinander selektiert. Die Datenextraktion und die Bewertung der methodischen Qualität wurden jeweils durch eine Autorin durchgeführt und von einer zweiten verifiziert. Für die methodische Qualitätsbewertung der eingeschlossenen randomisierten kontrollierten Studien (RCTs) wurde das Cochrane Risk of Bias Tool v.2 (RoB2) verwendet. Die Vertrauenswürdigkeit der Evidenz wurde nach dem GRADE-Bewertungsschema (Grading of Recommendations, Assessment, Development and Evaluations) eingestuft. Die Synthese der Studienergebnisse erfolgte narrativ.

Klinische Wirksamkeit

Für die Bewertung der klinischen Wirksamkeit wurden folgende Endpunkte herangezogen: Veränderung der Schmerzintensität, Veränderung der körperlichen Funktion, Veränderung von gelenkspezifischen Symptomen (z. B. Steifheit, Schwellung), Veränderung der gleichzeitigen Medikamenteneinnahme und Behandlung, Aktivitäten des täglichen Lebens, gesundheitsbezogene Lebensqualität, psychosoziale Endpunkte (z. B. Depression, Angstzustände, Schlafqualität) und technischer Erfolg des Eingriffs.

Sicherheit

Zur Bewertung der Sicherheit wurden folgende Endpunkte herangezogen: schwerwiegende unerwünschte Ereignisse (SUE) und unerwünschte Ereignisse (UE).

Ergebnisse

Verfügbare Evidenz

Es konnten drei randomisiert kontrollierte Studien (RCTs) mit 138 Patient:innen mit leichter bis moderater Gonarthrose eingeschlossen werden. Alle drei RCTs verglichen die genikuläre Arterienembolisation (GAE) mit einer Scheinembolisation (Sham). Das mittlere Alter der Studienteilnehmer:innen lag bei 57 bis 64 Jahren. Etwa 62 % der Teilnehmenden waren weiblich. Die Dauer der konservativen Therapien vor Studienbeginn variierte zwischen drei und sechs Monaten. Die Follow-up Dauer lag zwischen einem Monat und zwölf Monaten. Der primäre Endpunkt aller eingeschlossenen RCTs war die Reduktion der Schmerzintensität im Knie. In den eingeschlossenen RCTs wurden unterschiedliche Embolisate untersucht, darunter temporäre Substanzen wie Imipenem/Cilastatin und resorbierbare Partikel sowie Mikrosphären als permanentes Embolisat.

Es konnte keine Studie identifiziert werden, welche die Wirksamkeit und Sicherheit von TAPE bei Patient:innen mit Schulterarthrose untersuchte.

Klinische Wirksamkeit

Eine Studie zeigte einen Monat nach Embolisation eine signifikante Schmerzreduktion (gemessen mittels Visueller Analogskala (VAS)) zugunsten der GAE-Gruppe im Vergleich zur Scheinembolisation. Zu allen weiteren Erhebungszeitpunkten (1, 4, 6 und 12 Monate) zeigten sich unabhängig von den verwendeten Skalen (KOOS pain, VAS, Global change in knee pain) keine statistisch signifikanten Unterschiede zwischen den Gruppen.

Hinsichtlich der körperlichen Funktion wurde in einer Studie nach vier Monaten eine signifikante Verbesserung in der GAE-Gruppe im Vergleich zur Scheinembolisation beobachtet. Der 6-Minuten-Gehtest und der 30-Sekunden-Stuhlstandtest zeigten zu keinem Erhebungszeitpunkt statistisch signifikante Gruppenunterschiede.

Für gelenkspezifische Symptome, Aktivitäten des täglichen Lebens, gesundheitsbezogene Lebensqualität, Begleitmedikation und -therapie sowie psychosoziale Endpunkte (Angst, Depression) wurden zu keinem Zeitpunkt statistisch signifikante Unterschiede zwischen den Gruppen berichtet. In einer RCT wurde eine technische Erfolgsrate von 100 % für GAE berichtet.

Sicherheit

In keiner der eingeschlossenen RCTs wurden Ergebnisse zu SUE berichtet. Die aufgetretenen UEs waren überwiegend mild und selbstlimitierend. Zu den häufigsten UEs in den Behandlungsgruppen zählten vorübergehende Hautrötungen (transientes Erythem), Parästhesien im Bereich des lateralen Knöchels, Hämatome an der Einstichstelle in der Leiste sowie leichte Hauteinblutungen (Purpura). Die erfolgreiche Katheterisierung und Embolisation der Genikulararterien wurde in einer Studie berichtet und lag bei 100 %.

Laufende Studien

In den Studienregistern sind derzeit 15 laufende RCTs zu GAE im Vergleich zu Scheinbehandlung (n=12), Beobachtung (n=1) oder Standardbehandlung (n=2) aufgeführt. Die primären Endpunkte umfassen Schmerzen, Funktion, Steifheit, Aktivitäten des täglichen Lebens, gesundheitsbezogene Lebensqualität, Einnahme von Analgetika und Sicherheit. Das geplante Studienende der RCTs liegt zwischen 2026 und 2028. Es konnten keine registrierten laufenden Studien zu Schulterarthrose identifiziert werden.

Kostenerstattung

TAPE ist im österreichischen Leistungskatalog 2026 (Codierung ambulant) des Bundesministeriums für Arbeit, Soziales, Gesundheit, Pflege und Konsumentenschutz derzeit nicht enthalten. Daher wird diese Behandlung vom österreichischen Gesundheitssystem nicht vollständig erstattet.

Diskussion

Die Ergebnisse dieses Reviews zeigen, dass TAPE bei Patient:innen mit Kniearthrose zwar kurzfristig wirksam sein kann, die therapeutische Überlegenheit gegenüber einer Scheinbehandlung jedoch im Langzeitverlauf nicht konsistent nachweisbar ist. Der Placebo-Effekt invasiver Prozeduren ist bei Schmerzstudien hoch, was die fehlende Signifikanz in den Placebo-kontrollierten Langzeitdaten erklären könnte. Die Aussagekraft ist jedoch aufgrund mehreren Faktoren eingeschränkt: Mit nur drei RCTs und insgesamt 138 Patient:innen ist die statistische Präzision der Effektschätzung limit, sodass klinisch relevante Unterschiede nicht sicher ausgeschlossen werden können. Die Verwendung unterschiedlicher Embolisate (temporär vs. permanent) limitiert einen direkten Vergleich der Intervention. Des Weiteren weisen zwei RCTs methodische Schwächen auf. In der einen RCT wurden Patient:innen, die nach einem Monat nicht auf die Intervention ansprachen (non-responder) aus der Analyse ausgeschlossen bzw. erhielten zusätzliche Therapien, was zu einer Überschätzung der Wirksamkeit führen kann. In der zweiten RCT erfolgte eine Post-Randomisierung (vollständige versus punktuelle Embolisation von Genikulararterien) basierend auf dem technischen Erfolg der Embolisation, was die Aussage einer tatsächlichen Effektmodifikation einschränkt.

Schlussfolgerung

Die Evidenzbasis ist derzeit unzureichend, um eine verlässliche Beurteilung der Wirksamkeit und Sicherheit zu TAPE bei Patient:innen mit Kniearthrose gegenüber der Standardtherapie oder Scheinbehandlung im Routineeinsatz vornehmen zu können. Für TAPE zu Schulterarthrose liegen derzeit keine publizierten Studienergebnisse vor. Es besteht Forschungsbedarf an weiteren RCTs mit größeren Stichproben und längerer Nachbeobachtungsdauer.

1 Background

1.1 Overview of the disease, health condition and target population[1]

Indikation: Patient:innen mit chronischer symptomatischer Kniearthrose und Schulterarthrose

The target population for this assessment, as per the Classification of Diseases 11th Revision (ICD-11), is adult patients with chronic symptomatic knee osteoarthritis (gonarthrosis) (ICD-11 FA01 Osteoarthritis of knee) and shoulder (glenohumeral) osteoarthritis (ICD-11 FA03.Z Osteoarthritis of other specified joint, unspecified, XA05J7 Shoulder joint).

degenerative Gelenkerkrankung

multifaktorielle Ätiologie

Abbau, Erosion und Verdickung des Knorpels, Bildung von Osteophyten, Absterben der Knorpelzellen

Hauptlokalisation Knie

Osteoarthritis (OA) is a complex degenerative joint disease and represents one of the most prevalent causes of chronic disability due to pain and altered joint function in adults. The pathophysiology of OA is understood as a whole-joint disease, involving multiple anatomic and physiological alterations across all joint tissues, including articular cartilage degradation, subchondral bone remodelling, and synovial inflammation [1]. Its multifactorial aetiology involves a combination of systemic risk factors and local mechanical stress, which triggers a low-grade inflammatory process culminating in joint destruction. The disease typically begins with the breakdown and erosion of cartilage, leading to secondary changes such as thickening of the bone beneath the cartilage, the formation of bone spurs (osteophytes), and the death of cartilage cells. Concurrently, other joint tissues, such as the synovial lining, ligaments, and menisci, also become inflamed and damaged. In end-stage disease, the formation of calcium crystals may further exacerbate the inflammatory response [2-4]. The knee is one of the joints most affected by OA [5].

langsame Verschlechterung und Chronifizierung

The natural history of OA is characterised by a slow, progressive deterioration over many years. Initial symptoms are often mild and intermittent, evolving into more frequent and persistent pain over time [6]. The primary clinical manifestations include pain, stiffness, swelling, and limitations in joint function. The burden of OA extends beyond physical symptoms, adversely affecting psychosocial outcomes such as mental health, sleep quality, work productivity, and health-related quality of life (HRQoL) [1].

Alter als Hauptrisikofaktor

weitere Risikofaktoren: Diabetes, rheumatoide Arthritis, Gicht, körperliche Belastung, intensiver Sport, gelenkspezifische Verletzungen

Age is the most significant non-modifiable risk factor for OA. In addition to age, various personal and joint-specific risk factors contribute to the degenerative process. Personal risk factors predominantly include metabolic disorders such as diabetes mellitus and gout, obesity, rheumatoid arthritis, as well as participation in high-intensity sports, and significant occupational load. Joint-specific risk factors encompass local trauma (e.g., injuries, fractures), congenital or acquired deformities, and localised pathologies such as bacterial arthritis. Furthermore, the risk of developing OA increases with the cumulative number of comorbid conditions [7, 8].

[1] This section addresses the following assessment elements:
A0002 – What is the disease or health condition in the scope of this assessment?
A0003 – What are the known risk factors for the disease or health condition?
A0004 – What is the natural course of the disease or health condition?
A0005 – What is the burden of disease for patients with the disease or health condition?
A0006 – What are the consequences of the disease or health condition for the society?
A0007 – What is the target population in this assessment?
A0023 – How many people belong to the target population?

Einstufung Schweregrad Arthrose mittels radiologischer und klinischer Bewertungssysteme

The severity of OA is staged using both radiological and clinical scoring systems. The scores can be used to assess treatment outcomes and monitor progression in clinical studies. They are not suitable as the sole diagnostic criterion for therapeutic decision-making in OA, since the choice of therapy usually also depends on the individual symptom burden of the affected person, such as pain, functional impairment, and reduced quality of life [9].

radiologische Schweregradeinteilung: Kellgren-Lawrence-Score

For radiological staging, the four severity grades according to Kellgren and Lawrence (1957) [10] are suitable:

- **Grade I:** Joint space narrowing possible, osteophytes possible
- **Grade II:** Definite joint space narrowing, possible osteophytes, minimal sclerosis
- **Grade III:** Marked joint space narrowing, few osteophytes, mild sclerosis
- **Grade IV:** Severe joint space narrowing, large osteophytes, sclerosis, cysts, pronounced deformity

Saklen zur klinischen Schweregradeinteilung für Kniearthrose

For clinical staging, different scoring systems can be used. For knee OA, established scoring systems include the WOMAC-Score (Western Ontario and McMaster Universities Osteoarthritis Index) [11], Oxford Score [12], Knee Society Score [13], the Lequesne-Index (Lequesne Algofunctional Index) [14], or KOOS (Knee injury and Osteoarthritis Outcome Score) [15].

Skalen zur klinischen Schweregradeinteilung für Schulterarthrose

For shoulder OA, scores like the ASES (American Shoulder and Elbow Surgeons Score) [16], Constant-Mulrey-Score, SPADI (Shoulder Pain and Disability Index) [17], or UCLASS (University of California at Los Angeles Shoulder Score) [18] can be used.

595 Millionen Personen weltweit betroffen, Anstieg von 38 % bis 2080 in Österreich erwartet

Globally, OA represents a substantial global health burden. In 2020, an estimated 595 million people worldwide were affected, representing 7.6% of the global population [19]. Estimates for Austria indicate a 38% increase in the total number of OA patients by 2080, driven primarily by an ageing population. A significant demographic shift is anticipated, with the >80-year-old age group becoming the largest cohort, experiencing a projected 3.45-fold increase in male patients and a 2.48-fold increase in female patients compared to 2019 levels [20].

mit hohen indirekten Kosten verbunden aufgrund von Krankenständen und vorzeitigem Ruhestand

The economic and societal burden of OA is substantial and widely considered to be underestimated, accounting for an estimated 1-2.5% of the Gross National Product in high-income countries such as the United States, Canada, the United Kingdom, France, and Australia. A significant portion of these costs are indirect, attributable to productivity losses from sick leave and early retirement. This considerable economic impact is driven by the high prevalence of OA, the absence of cure, and the limited effective long-term treatment options [21].

1.2 Current clinical practice[2]

evidenzbasierte Leitlinien zur Diagnostik und Behandlung von Arthrose: NICE, AWMF

The current clinical pathway for the diagnosis and management of OA is guided by international evidence-based guidelines, primarily those from the UK's National Institute for Health and Care Excellence (NICE) for people with OA over 16 years old and from the German Society for Orthopaedics and Trauma Surgery (DGOU) S3 guideline of the Association of Scientific Medical Societies (AWMF) in Germany for the prevention and management of gonarthrosis. A multimodal, patient-centred approach is consistently recommended.

1.2.1 Diagnosis

Diagnose primär ohne bildgebende Verfahren

There is no gold standard for the clinical diagnosis of OA. Major guidelines advocate for a primarily clinical diagnosis, particularly in the absence of atypical features. For instance, the NICE guideline recommends diagnosing OA without imaging in patients who are ≥45 years of age, present with activity-related joint pain, and have morning stiffness lasting no longer than 30 minutes. In the absence of features suggestive of an alternative or concomitant diagnosis ("red flags") such as inflammatory arthritis or malignancy, the diagnosis can be established based on clinical history and examination alone [5].

NICE: Bildgebung nur bei atypischen Symptomen oder zur Stellung einer Differentialdiagnose

While imaging is often expected by patients, its routine use for diagnosis is discouraged, as a notable discordance often exists between radiological findings and symptom severity. Imaging is indicated only in cases with atypical presentations or when necessary for differential diagnosis (e.g., rheumatoid arthritis, other inflammatory joint conditions, or malignancy) [5, 22].

AWMF: Integrativer Diagnoseansatz: Anamnese, Untersuchung Röntgen

In contrast, the DGOU guideline for knee OA, while also emphasising clinical assessment, assigns a more integral role to imaging for diagnostic confirmation. It recommends an integrative approach combining medical history, clinical examination, and X-ray interpretation. However, imaging can be postponed in initial management. Especially in older adults, radiological findings often do not correlate well with the severity of symptoms. According to DGOU, imaging is primarily indicated when it has direct therapeutic consequences, such as planning for a surgical procedure, or is required for differential diagnosis (e.g., post-trauma) [9]. Additional and more specialised tests are only indicated in rare cases to clarify differential diagnoses. These include:

Magnetresonanztomographie (MRT), Computertomographie (CT), Labortests, Gelenkpunktion

- Magnetic resonance imaging (MRI), computed tomography (CT), or ultrasound: To evaluate soft tissues, cartilage damage, or bone structures.
- Laboratory tests (serology, inflammatory markers): To exclude systemic inflammatory rheumatic diseases.
- Joint aspiration with synovial fluid analysis: Indicated if septic arthritis or crystal arthropathy is suspected.

Biomarker im Serum und Urin nicht empfohlen

Both guidelines recommend that serum and urine biomarkers should currently not be used for routine diagnosis [9, 22].

[2] This section addresses the following assessment elements:
A0024 – How is the disease or health condition currently diagnosed according to published guidelines and in practice?
A0025 – How is the disease or health condition currently managed according to published guidelines and in practice?

1.2.2 Management

Both NICE and DGOU guidelines advocate a multimodal, patient-centred approach prioritising non-pharmacological interventions, with pharmacological treatments serving as adjuncts when indicated [5, 9].

multimodaler, patient:innenzentrierter Behandlungsansatz

Non-pharmacological interventions

The identified guidelines recommend therapeutic exercise tailored to individual needs as the cornerstone of OA management. Recommended modalities encompass local muscle strengthening and aerobic conditioning. Supervised therapeutic exercise sessions demonstrate superior outcomes for adherence and technique optimisation. Evidence supports combining therapeutic exercise with education programs or behaviour change approaches within structured treatment packages to enhance effectiveness and adherence [5, 9].

nicht-pharmakologische Interventionen als Erstlinientherapie

For patients with overweight and obesity, active weight loss interventions are recommended [5, 9]. It is advised that any amount of weight loss is beneficial, but a reduction of 10% of body weight is likely to be more effective than a 5% reduction [5].

Gewichtsreduktion bei Übergewicht und Adipositas

For patients with knee OA, manual therapy techniques, such as manipulation or mobilisation, should be considered exclusively as adjuncts to therapeutic exercise. Walking aids represent appropriate considerations for mobility support. However, routine prescription of orthotic devices (braces, insoles, tape, or splints) is not recommended. Their use is restricted to cases demonstrating joint instability where therapeutic exercise alone is ineffective, and the addition of the device is likely to improve function [5, 9].

orthopädische Hilfsmittel nicht routinemäßig empfohlen

The guidelines do not recommend acupuncture, dry needling or any modalities (e.g., transcutaneous electrical nerve stimulation, ultrasound, interferential therapy, laser therapy, pulsed shortwave therapy, neuromuscular electrical stimulation) for OA treatment [5, 9].

Akupunktur, trockenes Nadeln, physikalische Therapiemodalitäten nicht empfohlen

Pharmacological interventions

Pharmacological interventions are primarily indicated to support non-pharmacological management. They should be administered at the lowest effective dose for the shortest possible duration [5, 9].

pharmakologische Interventionen als Begleittherapie

The first-line pharmacological therapy is topical non-steroidal anti-inflammatory drugs (NSAIDs). Oral NSAIDs are recommended as a second-line treatment option if topical NSAIDs are ineffective or unsuitable. Prescription must involve a careful assessment of gastrointestinal, renal, hepatic, and cardiovascular risks, with co-prescription of a proton pump inhibitor is recommended. Intra-articular corticosteroid injections should be considered for short-term pain relief (typically 2-10 weeks) to manage flare-ups or facilitate physical therapy [5, 9].

nichtsteroidale Antirheumatika als Erstlinientherapie

The identified guidelines do not recommend routine use of paracetamol and all opioids (weak and strong). Their application is limited to infrequent, short-term pain relief only if all other pharmacological options are contraindicated, not tolerated, or ineffective. Glucosamine and intra-articular hyaluronic acid injection are explicitly not recommended for treatment of OA [5, 9].

eingeschränkte Empfehlung für Paracetamol und Opioide; Glucosamin und Hyaluronsäure nicht empfohlen

plättchenreiches Plasma, intraartikuläre Kortikosteroide bei Bedarf

The DGOU guideline recommends that platelet-rich plasma can be considered in patients with symptomatic knee OA if other analgesic and function-improving measures are not suitable, contraindicated or ineffective. Further, for patients with painful knee OA, a short-term treatment with intra-articular corticosteroids is recommended if other pharmacological treatment options are ineffective or unsuitable or if physical therapies could be supported [9].

Surgical joint replacement

künstlicher Gelenkersatz bei unwirksamen nicht-pharmakologischen Maßnahmen

Referral for joint replacement is recommended for people with knee or shoulder OA if their joint symptoms (such as pain, stiffness, reduced function or progressive joint deformity) are substantially impacting their quality of life and non-surgical management (e.g., therapeutic exercise, weight loss, pain relief) is ineffective or unsuitable [22].

1.3 Features of the intervention and comparators[3]

transarterielle periartikuläre Embolisation (TAPE): minimal-invasiv

Transarterial periarticular embolisation (TAPE) is a minimally invasive, catheter-based endovascular procedure. TAPE is indicated for the treatment of chronic joint pain associated with musculoskeletal conditions, such as OA, tendinopathy, and fasciopathy [23, 24].

digitale Subtraktionsangiographie (DAS), temporäre versus permanente Embolisation, Gefäßverschluss, Reduktion von Hypervaskularisation und Hyperperfusion

The procedure begins with visualising the vascular anatomy of the target joint using digital subtraction angiography via an arterial puncture and application of a contrast agent [23, 24]. The therapeutic mechanism involves selective embolisation of pathological neovessels within periarticular soft tissues, which contribute to local inflammatory processes and nociception. Embolisation is achieved through the delivery of embolic agents, categorised as either temporary (e.g., imipenem/cilastatin, resorbable particles) or permanent (e.g., non-resorbable microspheres). The resultant vascular occlusion aims to reduce pathological hypervascularisation and inflammatory hyperperfusion [25-27].

TAPE als Alternative bei konservativem Therapieversagen oder bei Kontraindikation für einen künstlichen Gelenkersatz

TAPE represents an alternative therapeutic option for patients with symptoms refractory to conservative treatment options, including physical therapy, exercise, weight loss, and pharmacological approaches, but who are either ineligible or unwilling to undergo surgical intervention [5, 28]. Current guidelines recommend a gradual escalation of conservative management strategies based on the patient's level of disease progression, functional impairment, and pain severity, before considering minimally invasive interventions for temporary symptom relief [26, 29].

[3] This section addresses the following assessment elements:
B0001 – What is the technology and the comparator(s)?
A0001 – For which health conditions, and for what purposes is the technology used?
A0020 – For which indications has the technology received marketing authorisation or CE marking?
B0002 – What is the claimed benefit of the technology in relation to the comparators?
B0003 – What is the phase of development and implementation of the technology and the comparator(s)?

künstlicher Gelenkersatz als Goldstandard bei Patient:innen mit schwerwiegender Kniearthrose

While total joint arthroplasty remains the gold standard treatment for severe knee OA, multiple contraindications preclude many patients from undergoing surgical treatment. Medical comorbidities, including diabetes mellitus, obesity, cardiovascular disease, malnutrition, kidney disease, hepatic cirrhosis, and immunosuppression, significantly elevate perioperative complication risks. Additionally, younger patients may face the high probability of requiring future revision surgeries, while the elderly may be too frail [26, 30, 31].

Embolisation der Kniegelenksarterien (GAE) bei Patient:innen >40 Jahren mit leichter bis schwerer Kniearthrose und anhaltenden Schmerzen (Visuelle Analogskala ≥40) trotz konservativer Therapie von 3 bis 6 Monaten

Genicular artery embolisation (GAE) is a novel treatment primarily indicated for patients over 40 years of age with mild-to-severe OA of the knee (Kellgren-Lawrence scores 1-4), persistent pain (visual analogue scale ≥40mm, range 0-100) despite at least three to six months of conservative therapy, and who are contraindicated to or refuse surgical intervention. The current consensus suggests that patients with mild-to-severe disease whose symptoms remain refractory to at least three months of conservative management may benefit from GAE, potentially avoiding or delaying surgery [32, 33]. Beyond knee OA, emerging evidence indicates that TAPE is effective for other musculoskeletal conditions, including arthritis of the fingers, rhizarthrosis, as well as elbow and shoulder pain[27, 34, 35].

keine CE-Zertifizierung oder Food and Drug Administration (FDA)-Zulassung notwendig

TAPE is a procedural intervention and not a medical device. Therefore, TAPE does not require CE marking or FDA approval.

Administration, Investments, personnel and tools required to use the technology and the comparator(s)[4]

Durchführung der GAE von interventionellen Radiolog:innen

GAE is performed as an elective outpatient procedure by an interventional radiologist in specialised interventional radiology centres. The procedure is typically conducted under minimal to moderate sedation combined with local anaesthesia, following institutional protocols and individual patient requirements [33].

Fluoroskopie und DSA notwendig, Sedierungsüberwachung

The interventional radiology centre must be equipped with advanced imaging capabilities, including fluoroscopy and digital subtraction angiography systems suitable for lower-extremity vascular interventions. Additionally, appropriate infrastructure for sedation monitoring and patient support is mandatory [33].

Absetzung von Antikoagulanzien oder Warfarin vor Eingriff

Prior to the intervention, comprehensive laboratory examinations are required. Anticoagulation management is essential, necessitating discontinuation of direct oral anticoagulants or warfarin 24-48 hours preprocedural, based on individual bleeding risk stratification. Standard prophylactic protocols comprise intravenous administration of cefazolin (2g) for infection prevention, ketorolac (30mg) for analgesia, and dexamethasone (10mg) for anti-inflammatory effects. Sedation and analgesic agents are titrated according to the selected sedation level and individual patient requirements [33].

[4] This section addresses the following assessment elements:
B0004 – Who administers the technology and the comparators and in what context and level of care are they provided?
B0008 – What kind of special premises are needed to use the technology and the comparator(s)?
B0009 – What supplies are needed to use the technology and the comparator(s)?

angiographische Darstellung mittels Kegelstrahl-CT und DSA, Kälte zur vorübergehenden Gefäßverengung

The procedure requires cone-beam CT integrated with power injector systems for contrast medium delivery, facilitating precise visualisation of arterial anatomy and identification of anatomical variants. Digital subtraction angiography provides essential real-time imaging for selective arterial catheterisation. Radiopaque markers may be utilised pre-procedurally to identify specific pain localisation points under fluoroscopic guidance. Some operators employ pre-procedural ice pack application to induce temporary vasoconstriction, demonstrating a reduction in non-target cutaneous embolisation from 57-65% to 11% [33].

Injektion des Embolisationsmaterials durch Mikrokatheter, temporäre versus permanente Embolisate

Vascular access instrumentation varies according to the selected approach (femoral, radial, or pedal artery). Microcatheters enable precise delivery of embolic agents to target vessels. The selection of embolic materials depends on regional availability and regulatory approval status. Imipenem/cilastatin, prepared as a mixture with iodinated contrast medium (0.5g in 5-10mL) with particle sizes ranging from 10-70µm, represents the most frequently utilised temporary embolic agent internationally. Permanent embolic agents include various microsphere formulations: Embozene (75-100µm), Embospheres (100-300µm), HydroPearl (200µm), and polyvinyl alcohol particles (10-70µm). Recent evidence indicates potentially superior outcomes with permanent particles, demonstrating greater pain reduction at one-month follow-up compared to imipenem/cilastatin [33].

Hämostase durch manuelle Kompression oder Gefäßverschlusssysteme

Haemostasis at the arterial access site is achieved through either manual compression (minimum 15 minutes) or deployment of vascular closure devices for immediate arteriotomy sealing. Post-procedural care includes administration of laxative agents to prevent straining, particularly relevant for patients requiring 4-6 hours of bed rest following manual compression. The complete procedure typically requires 1-2 hours, with most patients eligible for discharge within 4 hours post-intervention [33].

Regulatory & reimbursement status[5]

TAPE im österreichischen Leistungskatalog 2026 nicht inkludiert

The Austrian hospital benefit catalogue from 2026 [36] does not include TAPE for treatment of knee or shoulder OA. Therefore, it is not fully reimbursed by the Austrian healthcare system.

[5] This section addresses the following assessment elements:
A0021 – What is the reimbursement status of the technology?
A0011 – How much are the technologies utilised?

2 Objectives and Scope

2.1 PICO question

PIKO-Frage

What is the evidence for the effectiveness and safety of TAPE compared to conservative treatments (physical therapy, exercise, weight management), pharmacological treatment (e.g., NSAIDs, including Cox-2 inhibitors, acetaminophen, steroid injections) or surgical joint replacement in patients with knee or shoulder OA concerning pain intensity, physical function, pain medication intake, activities of daily living, joint symptoms, health-related quality of life, and psychosocial outcomes (e.g., depression, anxiety, sleep quality)?

2.2 Inclusion criteria

Einschlusskriterien für relevante Studien

Inclusion criteria for relevant studies are summarised in Table 2-1.

Table 2-1: Inclusion criteria

Population	Adult patients (≥ 18 years) diagnosed with symptomatic ■ knee osteoarthritis (gonarthrosis) *ICD-11 code*: FA01 – Osteoarthritis of knee *MeSH term*: Osteoarthritis, Knee C05.550.114.606.500, C05.799.613.500 ■ shoulder (glenohumeral) osteoarthritis *ICD-11 code*: FA03.Z-XA05J7 – Osteoarthritis of other specified joint, unspecified, shoulder joint (XA05J7) *MeSH terms*: Shoulder Joint A02.835.583.748, Osteoarthritis C05.550.114.606, C05.799.613
Intervention	■ Transarterial periarticular embolisation (TAPE) performed with either ■ temporary embolic agents (e.g., imipenem/cilastatin) or ■ permanent embolic agents (e.g., microspheres, polyvinyl alcohol) ■ Genicular artery embolisation (GAE) specifically for knee osteoarthritis *MeSH term*: Embolisation, Therapeutic E02.520.360, E02.926.500
Control	■ Non-pharmacological interventions: ■ Weight management *MeSH terms*: Weight Loss C23.888.144.243.963, G07.345.249.314.120.200.963, Diet, Reducing E02.642.249.285, G07.203.650.240.285, Weight Reduction Programs I02.233.332.445.650, N02.421.726.407.579.650 ■ Exercise *MeSH terms*: Exercise G11.427.410.698.277, I03.350, Exercise Therapy E02.760.169.063.500.387, E02.779.483, E02.831.535.483 ■ Physical therapy*MeSH term:* Physical Therapy Modalities E02.779, E02.831.535 ■ Pharmacological interventions: ■ Oral or topical nonsteroidal anti-inflammatory drugs (NSAIDs), including Cox-2 inhibitors *Mesh terms:* Anti-Inflammatory Agents, Non-Steroidal D27.505.696.663.850.014.040.500, D27.505.954.158.030, D27.505.954.329.030, Cyclooxygenase 2 Inhibitors D27.505.519.389.310.500, D27.505.696.663.850.014.040.500.500.500, D27.505.954.158.030.500.500, D27.505.954.329.030.500.500 ■ Acetaminophen *Mesh term:* Acetaminophen D02.065.199.092.040, D02.092.146.113.092.040 ■ Intra-articular injections (e.g., corticosteroids, hyaluronic acid) *MeSH term:* Injections, Intra-Articular E02.319.267.530.380 ■ Surgical joint replacement *MeSH term:* Arthroplasty, Replacement E04.555.110.110, E04.617.101.110, E04.650.110

Control *(continaution)*	**Rationale:** The most appropriate comparators are defined in the NICE guideline (2022) "Osteoarthritis in over 16s: diagnosis and management" [5] and S3-Guideline "Gonarthrose" from the German Society for Orthopedics and Trauma Surgery (2024) [9].
Outcomes	
Efficacy	*Primary efficacy outcomes:* ■ Change in pain intensity (at rest/during movement) ■ Change in physical function *Secondary efficacy outcomes:* ■ Change in symptoms (e.g., stiffness, swelling, grinding, hearing or clicking, catching or hanging up, stretching or bending of the joint) ■ Change in concurrent medication intake and treatment ■ Activities of daily living ■ Health-related quality of life (HRQoL) ■ Psychosocial outcomes (e.g., depression, anxiety, sleep quality) ■ Technical success **Rationale:** Informed by a scoping search of the literature.
Safety	■ Adverse events (AEs) ■ Serious adverse events (SAEs)
Study design	
Efficacy	■ Randomised controlled trials (RCTs) ■ Sham-controlled RCTs Prospective non-RCTs (if no RCTs available)
Safety	■ RCTs ■ Prospective non-RCTs (if no RCTs are available and sample size is at least 200 study participants)

3 Methods

3.1 Research questions

EUnetHTA Core Model®

Assessment elements from the European Network for Health Technology Assessment (EUnetHTA) Core Model® for the production of Rapid Relative Effectiveness Assessments (Version 4.2) were customised to the specific objectives of this assessment. Please refer to Appendix (Table A-6 to Table A-9) for the detailed research questions.

AIHTA Methodenleitlinie

The systematic review was conducted in accordance with the Austrian Institute for Health Technology Assessment (AIHTA) methodological guidance for individual medical procedures [37], which based on the EUnetHTA Core Model® [65] and the HTA-R methodological guidance documents [66]. The review protocol was pre-registered on the Open Science Framework platform [38].

3.2 Clinical effectiveness and safety

3.2.1 Systematic literature search

systematische Literatursuche in 4 Datenbanken

The systematic literature search was conducted on the 17th and 19th November 2025 in the following databases:

- MEDLINE via Ovid
- Embase
- The Cochrane Library
- International HTA Database (INAHTA)

insgesamt 1.220 Treffer

The systematic search was limited to articles published in English or German. After deduplication, an overall of 1,220 citations remained. The Medline search strategy is provided as an example in the Appendix. The other searches are published on Open Science Framework (OSF) [38].

Suche nach laufenden Studien

Furthermore, to identify ongoing and unpublished studies, a search in three clinical trials registries (ClinicalTrials.gov; WHO-ICTRP; EU Clinical Trials) was conducted on the 15.12.2025, resulting in 64 potentially relevant hits.

No additional studies were found by hand search.

3.2.2 Flow chart of study selection

Literaturauswahl

Overall, 1,220 studies were identified after de-duplication. The references were screened by two independent researchers, and in case of disagreement, a third researcher was involved in solving the differences. The selection process is displayed in Figure 3-1.

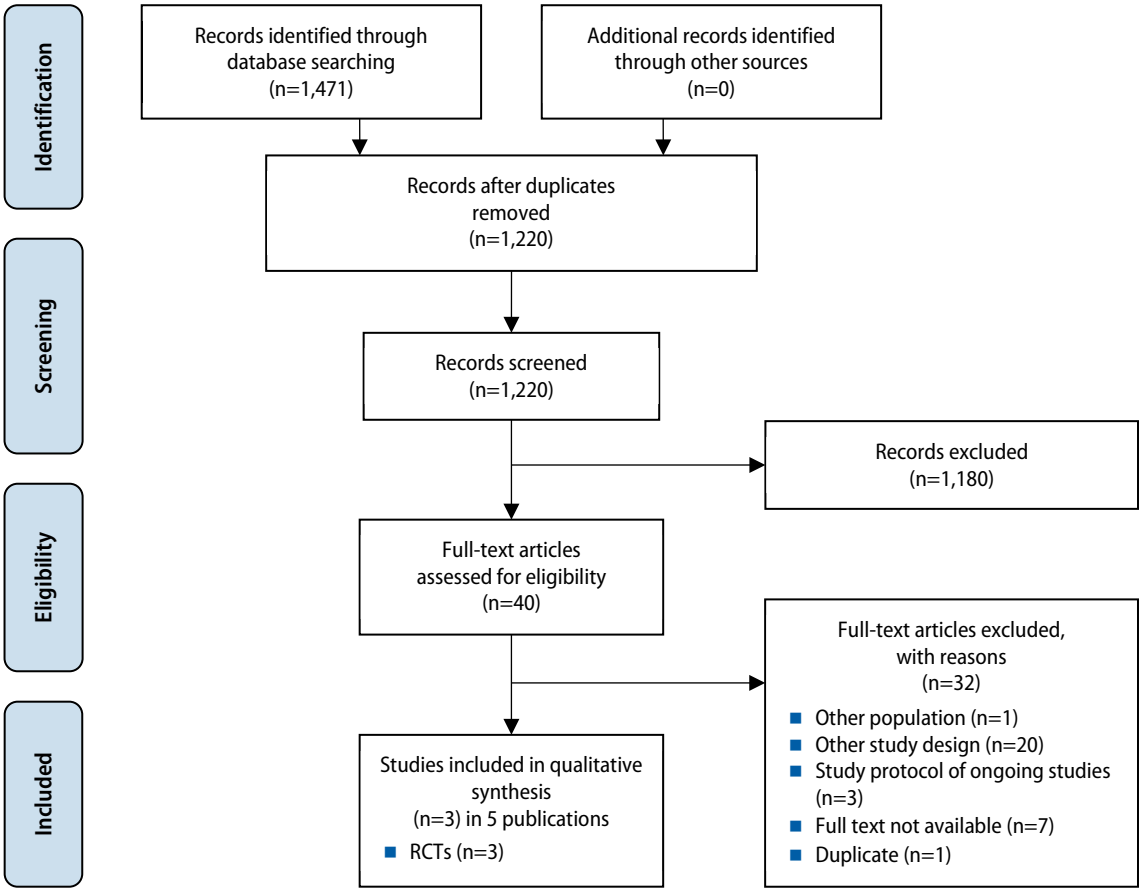

Figure 3-1: Flow chart of study selection (PRISMA Flow Diagram)

3.2.3 Analysis

Datenextraktion

Relevant data from included studies were extracted into piloted data extraction tables and cross-checked by a second author for accuracy.

Risk of Bias (RoB): Cochrane RoB 2 für RCTs

The internal validity of included studies was assessed using the Cochrane Risk of Bias (RoB) tool v.2 [39] for RCTs (see Table A-2).

3.2.4 Synthesis

qualitative Synthese der Evidenz mithilfe von GRADE

The questions were answered in plain text format with reference to GRADE evidence tables that are included in the Appendix, results were summarised in Table 4-1.

3.3 Outcomes

3.3.1 Outcomes effectiveness

The following outcomes were defined as *critical* to derive a recommendation:

entscheidungsrelevante Endpunkte für Wirksamkeit

- **Change in pain intensity (at rest/during movement):**

  Pain intensity can be measured by different scales. Different pain scales were accepted as they are all established measures for evaluating pain in OA:

  - *Knee Injury and Osteoarthritis Outcome Score (KOOS):*
    The KOOS is a patient-reported knee-specific questionnaire including 42 items in 5 subscales: pain (9 items), symptoms (7 items), function of daily living (17 items), sport and recreation function (5 items), and quality of life (4 items). The subscale pain can be used to assess pain intensity. In general, scores are transformed to a 0-100 scale, with 0 representing extreme knee problems and 100 representing no knee problems [40, 41].

    Schmerzintensität: KOOS – höhere Punktzahl bedeutet weniger Schmerzen

  - *Visual Analogue Scale (VAS):*
    The VAS measures subjective pain intensity using a 100-millimetre line scale. Patients rate their current pain level, whereas 0 represents "no pain" and 100 indicates "worst pain imaginable" [42].

    VAS – höhere Punktzahl bedeutet mehr Schmerzen

  - *Western Ontario McMaster Universities Osteoarthritis Index (WOMAC):*
    The WOMAC is a self-administered questionnaire consisting of 24 items divided into 3 subscales: pain (5 items), joint stiffness (2 items), and physical function (17 items). Initially, the WOMAC was developed for hip and knee OA. Higher scores on the WOMAC indicate greater disability and disease severity, i.e., pain and stiffness, as well as functional limitations [11].

    WOMAC – höhere Punktzahl bedeutet stärkere Einschränkung und höherer Schweregrad der Erkrankung

  - *Intermittent and Constant Osteoarthritis Pain (ICOAP):*
    The ICOAP is an 11-item measure that assesses pain in individuals with hip or knee OA. The questionnaire was developed to assess two forms of pain: intermittent and constant pain [43].

    ICOAP – höhere Punktzahl bedeutet mehr Schmerzen

- **Change in physical function:**

  körperliche Funktion:

  Physical function in patients with OA can be measured through different scales :

  KOOS – höhere Punktzahl bedeutet höhere körperliche Belastbarkeit bei einer sportlichen Aktivität

  - *KOOS – sport and recreating function subscale* [40, 41]
    6-Minuten-Gehtest
  - *6-minute-walking test*: The 6-minute walking test was originally designed to help in the assessment of patients with cardiopulmonary issues and has since been introduced for use in numerous other conditions. The 6-minute walking test is a low-intensity, submaximal exercise test used to assess aerobic capacity, endurance and oxygen saturation. The test evaluates objectively the functional impairment by measuring the maximum distance a patient can walk in six minutes [44].
  - *30-second chair stand test*:
    During the 30-second chair stand test, the patient completes as many sit-to-stand-to-sit repetitions as possible from a standardised-height chair within 30 seconds without using their arms [45].

    30-Sekunden-Stuhlstandtest

Additionally, the following outcomes were defined as *important* but not critical for decision-making:

wichtige Endpunkte für die Wirksamkeit: Veränderung der Symptomatik, Veränderung der Begleitmedikation und -behandlung, Aktivitäten des täglichen Lebens, gesundheitsbezogene Lebensqualität, psychosoziale Endpunkte, technischer Erfolg

- Change in symptoms (e.g., stiffness, swelling, grinding, hearing or clicking, catching or hanging up, stretching or bending of the joint)
- Change in concurrent medication intake and treatment
- Activities of daily living
- Health-related quality of life
- Psychosocial outcomes (e.g., depression, anxiety, sleep quality)
- Technical success

3.3.2 Outcomes safety

The following outcomes were defined as *crucial* to derive a recommendation:

entscheidungsrelevante Sicherheitsendpunkte

- Adverse events (AEs):
  An AE is defined as any untoward medical occurrence in a patient or clinical trial subject who has received a medicinal product and which does not necessarily have a causal relationship with this treatment. An adverse event can therefore be any unfavourable and unintended sign (including an abnormal laboratory finding, for example), symptom or disease temporally associated with the use of a medicinal product, whether or not considered related to the medicinal product [46].

  unerwünschte Ereignisse (UE)

  Serious adverse events (SAEs):
  A SAE event is defined as any untoward medical occurrence or effect that at any dose results in death, is life-threatening, requires hospitalisation or prolongation of existing hospitalisation, results in persistent or significant disability or incapacity, or is a congenital anomaly or birth defect. The severity of these events is determined by their outcomes rather than by the intensity of the medical occurrence itself [46].

  schwere unerwünschte Ereignisse (SAE)

3.4 Included studies

3.4.1 Included studies effectiveness

This section summarises the evidence specifically retrieved to evaluate the efficacy of GAE for the treatment of knee OA. No eligible studies investigating TAPE for shoulder OA met the inclusion criteria.

keine Studien für TAPE zu Schulterarthrose

A total of three RCTs met our pre-defined inclusion criteria for knee OA [47-49]. Study protocols were published for two of the three trials [50, 51]. The studies were published between 2022 and 2024, originating from the USA [49], Australia [48] and the Netherlands [47]. One trial was multi-centric [49], and two were conducted in a single centre [50, 51].

3 RCTs für TAPE zu Kniearthrose

All studies investigated the efficacy of GAE compared to sham embolisation. All studies targeted patients with mild-to-moderate knee OA, defined as Kellgren-Lawrence grades one to three in two studies [47, 49] and grade two in one [48]. The three studies included a total of 138 patients, with individual sample sizes of 21 [49], 58 [47] and 59 [48] patients. Mean ages varied between

insgesamt 138 Patient:innen: 72 in der Interventionsgruppe (IG) und 66 in der Kontrollgruppe (KG)

57.3 and 63.9 years. Approximately 62% of patients were female. While all studies required chronic knee pain refractory to conservative treatment, the conservative therapy duration varied from three [49] to six months [47, 48].

primärer Endpunkt: Reduktion der Schmerzintensität im Knie

One study [49] permitted cross-over to active treatment at one month for non-responders. Follow-up durations ranged from one to twelve months. The primary outcome across all three RCTs was the reduction of knee pain intensity, assessed using VAS, KOOS and/or ICOAP. Additionally, one study used a self-reported global change score of knee pain based on a 7-point Likert scale [48]. Further, one study evaluated the reduction of knee OA severity using the WOMAC score as the primary outcome [49].

Subgruppen-Analyse in 1 RCT: vollständige vs. punktuelle Embolisation

One study performed subgroup analyses comparing participants who received complete embolisation of all genicular arteries (as distinct from embolisation of some arteries) with the control group for KOOS and Global Change scores at twelvemonths. The definition of these subgroups was influenced by the fact that the intervention group procedure was adjusted early in the trial. Consequently, the first four intervention group participants had one genicular artery embolized by design. For the remaining intervention group participants, partial embolisation occurred only because vascular anatomy prevented catheterisation of specific vessels, for instance, due to the vessel's small diameter or acute direction change [48].

The technical procedure and embolic agents varied between the studies:

resorbierbare Partikel als Embolisationsmaterial (temporär)

Intervention durchgeführt von 3 interventionellen Radiolog:innen mit 7-9 Jahren Erfahrung

One study used a 2.4-F microcatheter to selectively catheterise genicular arteries perfusing the symptomatic side of the knee. Following selective digital subtraction angiography (DSA) at one to two frames/second, areas of pathological neovascularisation were identified as "tumour blush" on delayed images. Embolisation was performed using 100-300μm absorbable particles (OptiSphere; Teleflex), prepared by diluting 2mL particles in 18mL contrast material. Sequential 0.2mL aliquots were injected, each followed by repeat DSA, until the tumour blush disappeared. Follow-up angiography from the femoral artery excluded untreated branches. All patients received prophylactic antibiotics (pre-procedure and five days post-procedure), pain medication (up to one week), and were discharged two to three hours after the procedure using a closure device for hemostasis. All procedures were performed by three interventional radiologists with nine, seven, and seven years of experience performing embolisation procedures, respectively [49].

Imipenem/Cilastatin Sodium als Embolisationsmaterial (temporär)

Intervention durchgeführt von 1 interventionellen Radiolog:in mit 4 Jahren Erfahrung

The other study employed a 2.6-F microcatheter through a 3-F introducer sheath under light sedation and local anaesthesia. Uniquely, they used 0.5g imipenem/cilastatin sodium (Primaxin; Merck) suspended in 10mL iodinated contrast as the embolic agent, injected until blood flow stagnation was observed on angiogram. The protocol was modified after the first four participants: initially only the dominant neovessel-contributing vessel was embolized, but subsequent participants (n=25) underwent sequential assessment and embolisation of all accessible genicular arteries with visible neovessels, as additional vessels were observed to spontaneously open after embolisation of the dominant artery. In eight participants, one genicular artery (typically the superior medial genicular) could not be catheterized due to unfavourable anatomy. The intervention was conducted by one interventional radiologist who had four years of experience embolizing blood vessels for uncontrolled bleeding and had completed a TAPE pilot study in ten people with knee pain and OA [48].

The third study utilised a 4-Fr catheter system with a 1.8-Fr microcatheter via an anterograde approach after local anaesthesia (10mL 2% lidocaine). They systematically assessed eight genicular arteries (lateral superior, medial superior, lateral inferior, medial inferior, descending genicular, superior patellar, median genicular, and superior patellar recurrent arteries) using selective angiography to identify hyperaemic blush indicating angiogenesis. Embolisation was performed with 75μm or 100μm Embozene microspheres (Varian), targeting near-stasis of flow in hyperaemic areas while preserving normal vasculature. Ice packs were applied around the knee before embolisation to induce cutaneous vasoconstriction and reduce non-target embolisation. All procedures were performed by a single interventional radiologist with 15 years of experience [47].

embozene Mikrospären (permanent) als Embolisationsmaterial

Intervention durchgeführt von 1 interventionellen Radiolog:in mit 15 Jahren Erfahrung

The mean procedure time was reported in two studies: one study reported 108.2 minutes (± 21.7) in the treatment group compared to 91.9 minutes (± 18.5) in the sham group [47], while the other study reported 78.9 minutes (± 40.9) in the treatment group versus 29.9 minutes (± 15.8) in the sham group.

durchschnittliche Eingriffsdauer: 78,9 bis 108,2 Minuten in der IG und 29,9 bis 91,9 Minuten in der KG

Study characteristics and results of included studies are displayed in Table A-1 and Table A-2 and in the evidence profile in Table A-3.

3.4.2 Additional included studies safety

Results from the studies included for effectiveness outcomes were also included in the safety analyses. No additional studies were included.

keine zusätzlichen Studien für Sicherheitsendpunkte

3.5 Results

Morbidity[6]

Change in pain intensity

All studies investigated the reduction of knee pain after the use of GAE. The studies evaluated the change of pain intensity using KOOS [47, 48], VAS [47, 49], and ICOAP scores [47].

Veränderung der Schmerzintensität in 3 RCTs gemessen

In one study (n=58), the GAE group showed greater improvements than the sham group at four months across multiple pain scales, however none reached statistical significance. The KOOS pain subscale improved by 21.4 vs 18.4 (between-group difference: 3.0, 95% CI -7.1 to 13.0). VAS scores decreased more in the GAE group (-22.9 vs -13.83), with a between-group difference of –9.07 (95% CI –22.02 to 3.88). Both intermittent and constant pain (ICOAP) also showed greater reductions in the GAE group (between-group differences: –3.02, 95% CI –14.63 to 8.59, and –4.48, 95% CI –15.94 to 6.98, respectively). Changes in knee pain after one month were not reported [47].

keine signifikante Schmerzreduktion nach 4 Monaten gemessen mit KOOS Subskala Schmerz, VAS und ICOAP

[6] This section addresses the following assessment elements:
D0005 – How does the technology affect symptoms and findings (severity, frequency) of the disease or health condition?
D0006 – How does the technology affect progression (or recurrence) of the disease or health condition?

keine signifikante Schmerzreduktion nach 12 Monaten gemessen mit KOOS Subskala Schmerz

The other study (n=59) reported improvements in KOOS pain scores in the GAE group (41.3%) and in the sham group (29.4%). However, the differences were statistically not significant at 12 months follow-up. Global change in knee pain at 12 months indicated that 58.6% in the GAE group reported being moderately or much better, compared to 37.9% in the sham group (p=ns). Subgroup analyses (n=47) stratified by embolisation completeness (partial vs. complete) did not reveal statistically significant benefits over the control group for KOOS pain scores at any time point. While the proportion of participants reporting global improvement ('moderately or much better') appeared higher in the complete embolisation subgroup (76.5%) compared to controls (37.9%), this difference failed to reach statistical significance. Due to the non-randomised, intra-operative determination of these subgroups, these findings remain inconclusive [48].

signifikante Schmerzreduktion nach 1 Monat gemessen mit VAS

In contrast, the third study (n=21) reported a statistically significant between-group difference in VAS score reduction at one month of 50.1 points (95% CI 29 to 72.3, p<0.01), favouring GAE. However, between-group differences at subsequent follow-up time points (three, six, and twelve months) were not reported[49].

Change in symptoms

Veränderung der Symptomatik in 2 RCTs gemessen

Two studies (n=117) assessed changes in joint-specific symptoms using the KOOS symptoms subscale [47, 48], consisting of seven items evaluating the frequency and severity of issues like stiffness, swelling, catching or clicking in the knee [40, 41].

keine signifikante Symptomverbesserung nach 1, 4, 6 und 12 Monaten gemessen mit KOOS Subskala Symptome

One of the two studies (n=58) reported improvements in both groups at four months, with a non-significant between-group difference of 2.34 (95% CI –7.92 to 12.60) [47]. Similarly, the other study (n=59) found no significant differences at one month (2.2, 95% CI –6.9 to 11.4), six months (–3.2, 95% CI –20.7 to 14.4), and twelve months (9.3, 95% CI –7.2 to 25.8). Furthermore, subgroup analysis of patients receiving complete embolisation (n=47) showed no significant difference in symptom reduction compared to the sham group [48].

Change in the severity of knee OA

signifikante Verbesserung des Schweregrades von Kniearthrose nach 1 Monat gemessen mit WOMAC

One study (n=21) measured the severity of knee OA with the WOMAC. Disability improvement was significantly greater in the GAE group with 25.2 points (95% CI, 3.5 to 45.9, p=0.02) compared to the sham group at one month. In addition, the WOMAC subscore comparisons between the GAE group and sham group revealed also significant differences in all three subscores (pain, joint stiffness, functional limitations). When comparing the reduction in the total WOMAC score at one month in the crossover group and that in the sham group, the difference was 14.6 (95% CI, –9.7 to 38.8) and was not significant. Additionally, the WOMAC subscore comparison between the crossover and sham group was significant for stiffness [49].

Function[7]

Physical function

körperliche Funktion in 2 RCTs gemessen

Two studies (n=117) assessed physical function using multiple outcome measures [47, 48].

signifikante Verbesserung nach 4 Monaten, keine signifikante Verbesserung nach 1, 6 und 12 Monaten gemessen mit KOOS Subskala sportliche Aktivitäten/Freizeit

Both studies evaluated physical function using the KOOS sports and recreation function subscale, with differing results. One study (n=58) demonstrated a statistically significant between-group difference of 12.08 points (95% CI 0.70 to 23.45; p=0.04) at four months, favouring the GAE group. The GAE group improved by 22.32 points (95% CI 14.21 to 30.43) compared to 10.24 points (95% CI 2.25 to 18.23) in the sham group [47]. In contrast, the other study (n=59) found no significant between-group differences at one month (0.4, 95% CI –23.2 to 23.9), six months (4.3, 95% CI –20.1 to 28.7), or twelve months (n=47; 12.5, 95% CI –15.8 to 40.8). However, the subgroup analysis of patients receiving complete embolisation (n=47) of all genicular arteries showed a statistically significant difference between the GAE and sham group [48].

keine signifikante Verbesserung bei 6-Minuten-Gehtest und 30-Sekunden-Stuhlstandtest gemessen nach 1, 6 und 12 Monaten

The other study additionally assessed functional performance using the 6-minute-walking test and 30-second-chair-stand test. For the 6-minute-walking test, between-group differences were 13 meters (95% CI –34 to 59) at one month (n=59), –18 meters (95% CI -62 to 25) at six months (n=52), and six meters (95% CI –66 to 79) at twelve months (n=12), none of which were statistically significant. Similarly, the 30-second-chair-stand test showed non-significant differences of 0.9 repetitions (95% CI –0.7 to 2.4) at one month (n=59), –1.0 (95% CI –3.1 to 1.1) at six months (n=52), and 0.8 (95% CI –2.2 to 3.7) at twelve months (n=47) [48].

kein signifikanter Unterschied zwischen IG und KG bei Nutzung von Physiotherapie

One study (n=58) (2024) further reported the number of patients receiving physiotherapy in the GAE group versus the sham group at baseline (5 vs 4), one month (3 vs 2), and four months (2 vs 4), with no significant between-group differences observed [47].

Activities of daily living

Aktivitäten des täglichen Lebens (ADLs) in 2 RCTs gemessen

Two studies (n=117) assessed activities of daily living (ADL) using the KOOS ADL subscale [47, 48].

keine signifikante Verbesserung der ADLs nach 1, 4, 6 und 12 Monaten gemessen mit KOOS Subskala ADLs

In one study (n=58), the GAE group showed numerically greater improvement in KOOS ADL scores at four months compared to sham (21.27 vs 15.75 points), with a between-group difference of 5.52 (95% CI –4.82 to 15.86). However, the difference was statistically not significant[47].

The other study (n=59) found no significant between-group differences in ADL for patients receiving partial embolisation at one month (-1.5, 95% CI –18.2 to 15.3), six months (–6.1, 95% CI –23.9 to 11.6) and twelve months (7.4, 95% CI –9.2 to 23.9). Subgroup analysis indicated that patients receiving complete embolisation showed no significant difference compared to sham embolisation [48].

[7] This section addresses the following assessment elements:
D0011 – What is the effect of the technology on patients' body functions?
D0016 – How does the use of technology affect activities of daily living?

Change in concurrent medication intake and treatment

Veränderung von Begleitmedikation und -behandlung in 2 RCTs gemessen

Two studies (n=117) assessed changes in concurrent analgesic use and additional treatment [47, 48].

keine signifikanten Unterschiede gemessen

One study (n=59) reported comparable baseline analgesic use between groups (control: 80%, intervention: 72%; p=ns). At twelve months, the proportion of patients taking analgesics was lower in the GAE group (24%) compared to the control group (48%), though this difference did not reach statistical significance. Regarding additional treatments, six control group participants initiated new therapies (physiotherapy/exercise: n=4, arthroscopy: n=1, knee brace: n=1). One control patient underwent total knee arthroplasty after six months. In contrast, 13 participants in the GAE group commenced new non-surgical treatments (physiotherapy/exercise: n=12, corticosteroid injection: n=1) [48].

The other study (n=58) found no significant differences in concurrent medication use between the GAE and sham group at any follow-up time point [47].

Psychosocial outcomes

keine signifikante Verbesserung von Depression und Angst

Psychosocial outcomes were assessed in one study (n=59), evaluating anxiety and depression using the Hospital Anxiety and Depression Scale (HADS). Neither anxiety nor depression scores showed statistically significant differences between the GAE and sham group at any follow-up time point (one, six, and twelve months) [48].

Health-related quality of life[8]

Health-related quality of life (HRQoL)

gesundheitsbezogene Lebensqualität in 2 RCTs gemessen

HRQoL was evaluated in two RCTs (n=117) using different instruments: the EQ-5D-5L questionnaire [47] and the KOOS quality of life subscale [47, 48].

keine signifikante Verbesserung berichtet

No study reported statistically significant differences between the GAE groups and sham groups [47, 48]. The subgroup analysis investigating complete embolisation versus sham embolisation demonstrated significant higher KOOS quality of life scores compared to controls [48].

[8] This section addresses the following assessment elements:
D0012 – What is the effect of the technology on generic health-related quality of life?
D0013 – What is the effect of the technology on disease-specific quality of life?

Patient safety[9]

SAEs after GAE were not reported in any of the included RCTs. Most AEs were mild and self-limiting. The most common AEs in the treatment groups were transient skin erythema (n=11), persistent paraesthesia of the lateral ankle (n=2) [47], groin bruising near the incision site (n=5) [48], and purpura (n=3) [49].

keine SUEs berichtet, überwiegend milde und selbstlimitierende UEs

Technical success was reported in one study (n=21) and was achieved in all GAEs and sham procedures [49].

100 % technischer Erfolg in einer Studie

[9] This section addresses the following assessment elements:
C0008 – How safe is the technology in comparison to the comparator(s)?
C0002 – Are the harms related to dosage or frequency of applying the technology?
C0004 – How does the frequency or severity of harms change over time or in different settings?
C0005 – What are the susceptible patient groups that are more likely to be harmed through the use of the technology?
C0007 – Are the technology and comparator(s) associated with user-dependent harms?

4 Certainty of evidence

RoB mit Cochrane RoB 2 bewertet

Risk of bias (RoB) for individual studies was assessed with the Cochrane Risk of Bias 2 (RoB2) tool [39] and is presented in Table A-2 in the Appendix.

RoB niedrig in 1 RCT, einige Bedenken in 2 RCTs

Nearly all RoB domains were rated as low risk, particularly those related to the randomisation process, measurement of outcomes and selection of the reported results. In one study [49], there were some concerns due to some missing outcome data for the long-term follow-up, primarily resulting from the crossover after one month. Considering the already limited sample size, the resulting missing data further reduced the interpretability of the long-term results. In another study, some concerns were also detected because the subgroup analysis (complete vs. sham embolisation) was determined after the randomisation based on the technical success of the intervention. The classification into partial embolisation vs. complete embolisation only became apparent during the procedure. Although the anatomy (thin vessel) was of course already present beforehand, the status of the variable was only determined when the radiologist attempted to insert the catheter and failed [48].

Vertrauenswürdigkeit der Evidenz nach GRADE

The strength of evidence was rated according to the GRADE (Grading of Recommendations Assessment, Development and Evaluation) Schema [52] for each endpoint individually. Each study was rated by two independent researchers. In case of disagreement, a third researcher was involved to resolve the difference. A more detailed list of criteria applied can be found in the recommendations of the GRADE Working Group [1].

GRADE uses four categories to rank the strength of evidence:

- **High** = We are very confident that the true effect lies close to that of the estimate of the effect;
- **Moderate** = We are moderately confident in the effect estimate: the true effect is likely to be close to the estimate of the effect, but there is a possibility that it is substantially different;
- **Low** = Our confidence in the effect estimate is limited: the true effect may be substantially different from the estimate of the effect;
- **Very low** = Evidence either is unavailable or does not permit a conclusion.

The ranking according to the GRADE scheme for the research question can be found in the summary of findings table below and in the evidence profile in Appendix Table A-3.

Overall, the strength of evidence for the effectiveness and safety of GAE in comparison to sham embolisation is low.

Table 4-1: Summary of findings table of GAE

Outcome	Anticipated absolute effects (GAE vs sham embolisation)	Relative effect (95% CI)	Number of participants (studies)	Certainty of evidence	Comments
Efficacy					
Change in pain intensity	**KOOS pain** (2 RCTs): ■ No statistically significant between-group difference at 4 months (1 RCT, n=58). ■ No statistically significant between-group difference at 12 months in patients receiving partial and complete embolisation (1 RCT, n=59). ■ Significance level not reported at 1 month and 6 months in patients receiving partial embolisation (1 RCT, n=59). **VAS** (2 RCTs): ■ Statistically significant between-group difference in favour of the GAE group at 1-month follow-up (1 RCT, n=21). ■ No statistically significant between-group difference at 4 months (1 RCT, n=58). **Global change in knee pain:** (1 RCT, n=59): ■ No statistically significant between-group difference at any follow-up time point (1, 6, 12 months).	-	138 (3 RCTs)	⨁⨁◯◯ Low	Measured with KOOS pain subscale, VAS
Change in physical function	**KOOS sport and recreation function** (2 RCTs): ■ Statistically significant between-group difference in favour of the GAE group at 4 months follow-up (1 RCT, n=58). ■ Statistically significant between-group difference in favour of the GAE group at 12 months follow-up in patients receiving complete embolisation (1 RCT, n=47). ■ No statistically significant between-group difference at follow-up time points of 1, 6, and 12 months in patients receiving partial embolisation (1 RCT, n=59). **6MWT** (1 RCT): ■ No statistically significant between-group difference at any of the follow-up time points: 1 month (n=59), 6 months (n=52), and 12 months (n=47). **30-sec CST** (1 RCT): ■ No statistically significant between-group difference at any of the follow-up time points: 1 month (n=59), 6 months (n=52), and 12 months (n=47).	-	117 (2 RCTs)	⨁⨁◯◯ Low	Measured with KOOS sports and recreation function subscale, 6MWT, 30-sec CST
Change in symptoms	**KOOS symptoms** (2 RCTs): ■ No statistically significant between-group difference at 1 month (1 RCT, n=59), 4 months (1 RCT, n=58), 6 months (1 RCT, n=59) and 12 months (1 RCT, n=59) in patients receiving partial or complete embolisation. **WOMAC** (1 RCT, n=21): ■ Statistically significant between-group difference in favour of the GAE group at 1 month follow-up. ■ Between-group difference not reported at 3, 6 and 12 months follow-up time points.	-	138 (3 RCTs)	⨁⨁◯◯ Low	Measured with KOOS symptoms subscale, WOMAC

Outcome	Anticipated absolute effects (GAE vs sham embolisation)	Relative effect (95% CI)	Number of participants (studies)	Certainty of evidence	Comments
Activities of daily living	**KOOS ADL** (2 RCTs): ■ No statistically significant between-group difference at 1 month (1 RCT, n=59), 4 months (1 RCT, n=58), 6 months (1 RCT, n=59) and 12 months (1 RCT, n=59) in patients receiving partial or complete embolisation.	-	117 (2 RCTs)	⨁⨁◯◯ Low	Measured with KOOS ADL function subscale
Health-related quality of life	**KOOS quality of life** (1 RCT, n=59): ■ No statistically significant between-group difference at 1 month, 6 and 12 months in patients receiving partial embolisation. ■ Statistically significant between-group difference in favour of the GAE group at 12 months follow-up in patients receiving complete embolisation. **EQ-5D-5L** (1 RCT, n=58): ■ No statistically significant between-group difference at 4 months.	-	117 (2 RCTs)	⨁⨁◯◯ Low	Measured with KOOS quality of life subscale, EQ-5D-5L
Anxiety	**HADS-A:** ■ No statistically significant between-group difference at 1 month, 6 and 12 months in patients receiving partial embolisation.	-	59 (1 RCT)	⨁⨁◯◯ Low	Measured with HADS Anxiety
Depression	**HADS-D:** ■ No statistically significant between-group difference at 1 month, 6 and 12 months in patients receiving partial embolisation.	-	59 (1 RCT)	⨁⨁◯◯ Low	Measured with HADS Depression
Change in concurrent medication intake and treatment	**Concurrent medications:** ■ No statistically significant between-group difference at 1 month, 4 months (1 RCT, n=58) and 12 months (1 RCT, n=59). **Concurrent treatment:** ■ Patients received concurrent treatment in the GAE group: (physiotherapy/exercise (n=12), corticosteroid injection (n=1)) and in the sham group (physiotherapy/exercise (n=4), arthroscopy (n=1), knee brace (n=1), knee arthroplasty (n=1).	-	117 (2 RCTs)	⨁⨁◯◯ Low	-
Safety					
Adverse events	In total, 37 AEs in the GAE group and 9 AEs in the control group were reported in the studies. Most reported AEs in the study arms were: ■ GAE group: skin erythema (n=11), groin bruising near the incision site (n=4), purpura (n=3), paraesthesia of the lateral ankle at the treated side (n=2), knee pain (n=1), nausea/vomiting (n=1) ■ Sham embolisation: groin bruising near the incision site (n=1), hematoma (n=1), ecchymosis (n=1), bleeding at access site (n=1)	-	138 (3 RCTs)	⨁⨁◯◯ Low	Not all AEs occurred in the studies were reported.
Serious adverse events	see comment	-	138 (3 RCTs)	⨁⨁◯◯ Low	No SAEs reported in any of the study arms up to any follow-up time point.

Abbreviations: ADL … Activities of daily living, AE … Adverse event, EQ-5D-5L … European Quality of Life 5 Dimensions 5 Level Version GAE … Genicular artery embolisation, HADS … Hospital Anxiety and Depression Scale, KOOS … Knee Injury and Osteoarthritis Outcome Score, RCT … Randomised controlled trial, SAE … Serious adverse event, WOMAC … Western Ontario and McMaster Universities Osteoarthritis Index, 6MWT … 6 minute walk test, 30-sec CST … 30 second chair stand

5 Discussion

Summary of findings

Ziel: Wirksamkeit und Sicherheit von TAPE bei Knie- und Schulterarthrose

The objective of this review was to assess the clinical effectiveness and safety of transarterial periarticular embolisation (TAPE) for treating patients with symptomatic knee and shoulder osteoarthritis (OA) compared to conservative treatment options (physical therapy, exercise, weight management), pharmacological treatment options or surgical joint replacement. A total of three RCTs met the pre-defined inclusion criteria, all investigating GAE in patients with knee OA compared to sham embolisation.

keine Studie zu Schulterarthrose

No studies could be identified evaluating the effectiveness and safety of TAPE in patients with shoulder OA.

3 RCTs mit insgesamt 138 Patient:innen mit Kniearthrose eingeschlossen

The included studies enrolled a total of 138 patients with moderate to severe knee OA, with follow-up durations ranging from one to twelve months. The RCTs evaluated different embolic agents, namely embozene microspheres, imipenem/cilastatin sodium, and micron absorbable particles. In terms of pain relief, one study demonstrated statistically significant pain reduction and improvement of knee OA severity at one month, favouring genicular artery embolisation (GAE) in comparison to sham embolisation, while another study did not reach statistical significance. The remaining studies did not report on this timepoint. Furthermore, between-group differences at long-term follow-up (four, six, and twelve months) showed no significant improvements. Statistically significant improvements in physical function were observed at four months in one study. Furthermore, a significant improvement in the combined endpoint of pain, stiffness, and functional limitation was observed at one month. No study reported significant improvements in joint-specific symptoms, activities of daily living, anxiety, or depression at any follow-up time point. Safety data indicated that GAE was generally well-tolerated, with most adverse events being mild and self-limiting.

signifikante Schmerzreduktion nach 1 Monat

signifikante Verbesserung der körperlichen Funktion nach 4 Monaten

Interpretation

Internal validity, external validity and evidence gaps

RoB: niedrig (1 RCT), einige Bedenken (2 RCTs)

The internal validity of the RCTs was assessed with the Cochrane RoB2. Most risk of bias domains were rated as low risk, particularly those related to the randomisation process, measurement of outcomes, and selective reporting. However, one study was judged to have some concerns due to missing outcome data. Patients in the sham group did not show improvement and were crossed over to GAE after one month. The non-responders of GAE, the patients who required additional pain therapy beyond their baseline regimen, represent treatment failures. By excluding these patients, the reported outcomes appear more favourable than they actually are, as the results only reflect improvements among responders rather than the entire patient population. While a sensitivity analysis was performed, the exclusion of non-responders means that reported improvements should be interpreted as what can be expected for responders rather than for the entire population undergoing GAE. The crossover approach could have lead to an exaggeration of the treatment effect [49].

einige Bedenken aufgrund einer potenziellen Überschätzung des Behandlungseffekts (1 RCT)

einige Bedenken aufgrund einer Abweichung von der geplanten Intervention, Post-Randomisierungs-Subgruppenanalyse (1 RCT)

Another study was also judged with some concerns due to deviations from the intended intervention. The subgroup analysis (complete vs. partial embolisation) was determined after the randomisation based on the technical success of the intervention. Specifically, for the majority of participants, the intention was to perform complete embolisation. However, in eight cases, vascular anatomy (e.g., small diameter) prevented catheterisation. Thus, the classification into 'partial' versus 'complete' was driven by intra-operative anatomical constraints rather than baseline characteristics, indicating a low credible effect modification [48]. However, the subgroup analysis showed statistically significant improvements in some outcomes (physical function, quality of life, and global change in knee pain). These findings indicate an evidence gap and provide a preliminary indication that the extent of embolisation may be a relevant factor for therapeutic efficacy. As only one study examined these subgroup effects, future randomised controlled trials (RCTs) are needed to prospectively evaluate the impact of technical success and completeness of embolisation to confirm this hypothesis.

Generalisierbarkeit eingeschränkt aufgrund wenigen RCTs und kleiner Stichprobengröße

Some factors limit the external validity. Most importantly, the low number of RCTs (n=3) and relatively small sample sizes (total n=138) substantially restrict generalisability and reduce statistical power to detect clinically meaningful differences.

möglicher Placebo-Effekt

Furthermore, invasive procedures have a larger placebo effect, possibly because patients perceive an invasive procedure as more effective and hence develop greater expectations of relief [53].

Generalisierbarkeit eingeschränkt aufgrund unterschiedlicher Embolisate und Kathetersysteme

Additionally, the heterogeneity in procedural techniques across studies, including different embolic agents (embozene microspheres, absorbable particles, imipenem/cilastatin sodium), and catheter systems, raises questions about which technical approach may be most effective and whether results from one technique can be generalised to others.

Hinweise auf bessere Wirksamkeit bei vollständiger Embolisation

Further, only one study [48] investigated the effectiveness of complete embolisation of all genicular arteries, demonstrating significantly better improvements in physical function and quality of life compared to controls. This finding indicates that achieving more complete embolisation may be critical to maximising functional outcomes.

unterschiedliche Erfahrungen und Anzahl der Operateur:innen

All procedures across the three RCTs were performed by experienced interventional radiologists with four to 15 years of experience in embolisation procedures. However, two of the three trials relied on a single operator each, while only one trial involved three operators. This predominance of single-operator studies limits the assessment of operator-dependent variability and raises questions about reproducibility across different clinical settings.

Diskrepanz zwischen Selektion der Patient:innen und Wirkmechanismus

Patient selection criteria may have influenced the applicability of results, as patients were selected based on symptoms and Kellgren-Lawrence grade rather than the presence or severity of synovitis, despite the hypothesised mechanism of GAE relying on reduction of synovitis and pain stimuli through embolisation of angiogenesis and subsequent perivascular sensory nerve hypoxia. The inclusion of patients with minimal or no synovitis may have diminished the likelihood of detecting a discernible effect of GAE.

mangelnde Kontrolle von Begleitmedikation oder -behandlung in einer RCT

Furthermore, the lack of standardisation across studies regarding concurrent treatments and medications limits comparability and generalisability. One study [48] monitored but did not control participants' use of medications or concurrent treatments during follow-up, which could have influenced outcomes. Additionally, while participants were required to have completed at

least six months of conservative treatment prior to intervention, the timing and type of these treatments were not systematically recorded or compared between groups.

Endpunkt-Erhebung mit unterschiedlichen Skalen

A further limitation concerns the heterogeneity of outcome measurements across the included studies, limiting the comparability of the findings.

Evidenzlücken

Several important evidence gaps were identified. Long-term effectiveness remains uncertain, with only one study reporting between-group differences at twelve months [48]. The long-term effect of symptom improvement and potential need for repeat procedures remains unknown. Furthermore, more studies are needed that investigate the effectiveness and safety of complete versus partial embolisation.

keine Studie zu Schulterarthrose identifiziert

Despite it being included in the review scope, no studies investigating TAPE for shoulder OA were identified, representing a complete evidence gap for this indication. This should be investigated in future studies.

Embedding our findings into existing knowledge

Systematische Reviews zu GAE

A total of ten systematic reviews (SRs) on GAE for knee OA were identified [25, 54-61]. While the majority included various study designs (RCTs, prospective and retrospective studies, cohort studies, and case reports), two reviews restricted their analysis to RCTs only [58, 59], equal to the present report. Additionally, two reviews incorporated cost-effectiveness analyses [58, 61].

bessere methodische Qualität im vorliegenden systematischen Review

The SR by Milhelm et al. 2025 [59], which included the identical three RCTs, aligned with the findings of this report in concluding that GAE provides short-term symptomatic pain relief as the primary benefit of GAE, while emphasising that limited sample sizes, methodological variability, and short follow-up periods constrain definitive conclusions. However, the risk of bias in this SR was assessed as high using the Risk of Bias Assessment Tool for Systematic Reviews (ROBIS) [62], as the review protocol was registered after the literature search was conducted. Furhtermore, the literature search is ambiguous due to inconsistent reporting of the databases used in the text and PRISMA flow chart. In contrast, the present SR provides a more transparent and robust methodological approach, as the GRADE framework was used to systematically assess the certainty of evidence.

Kosten-Effektivität basierend auf derzeitiger Evidenz nicht abschätzbar und abhängig vom Gesundheitssystem

Economic analyses of GAE were performed in two studies: One study investigated the cost-effectiveness from the Spanish National Health System and revealed that GAE increases costs and that its cost-effectiveness cannot be determined based on current evidence. Their cost analysis revealed an incremental cost of €3,432.37 per patient, requiring a health improvement of 0.137 quality-adjusted life years (QALY) per patient for GAE to be deemed cost-effective [58]. A US-based analysis compared GAE with radiofrequency ablation (RFA) and corticosteroid injections, finding that although RFA showed larger treatment effects, GAE demonstrated higher cost-effectiveness probability (41.6–54.8% vs 18.4–29.2%) with incremental cost-effectiveness ratios of $561–1,563 per QALY versus corticosteroids. These analyses underscore that cost-effectiveness remains uncertain and highly dependent on healthcare system context, comparator interventions, and patient selection – factors requiring further investigation [61].

Ongoing randomised controlled trials

A total of 15 ongoing RCTs comparing TAPE with sham treatment (n=12), observation (counselling on conservative management with a referral or prescription for physical therapy; n=1) or standard care (n=2) are listed in the trial registers, with primary endpoints including pain, function, stiffness, activities of daily living, quality of life, analgesia usage and safety. The planned study completion dates are between 2026 and 2028. The planned sample sizes are between 18 and 264 patients. A total of three studies from 2024 and 2025 have been completed, but no results have been published so far. No registered ongoing trials addressing shoulder OA could be identified. The list of ongoing studies is presented in Table A-5.

insgesamt 15 laufende RCTs zu GAE, keine Studie zu Schulterarthrose

Limitations

This report is limited by the lack of performing a meta-analysis, precluding a quantitative synthesis of the available evidence. However, given the limited number of studies, a qualitative synthesis was deemed more appropriate. Further, only published study data were used; unpublished raw data from the included trials and individual patient data were not available. However, the inclusion of peer-reviewed RCTs allows for a standardised assessment of validity and risk of bias. Finally, the literature search was restricted to studies published in English or German, potentially excluding relevant studies published in other languages. However, it is unlikely that pivotal high-quality RCTs were missed, as English serves as the primary language for major medical publications. A further limitation is a deviation from the methodological standard protocol of this systematic review: due to limited resources, a preliminary search for existing systematic reviews was not conducted.

Limitationen: keine Meta-Analyse

nur publizierte Daten

nur Publikationen in englischer und deutscher Sprache

Abweichung vom Protokoll: keine systematische Vorabrecherche nach SRs

Conclusion

The findings of this review highlight the need for larger, longer-term RCTs with prolonged blinding to accurately determine the added benefit of GAE compared to sham embolisation. Furthermore, future studies should investigate the specific effect of complete embolisation of all genicular arteries compared to partial embolisation to validate the preliminary signals of efficacy observed in the subgroup analysis in one study.

mehr Studien notwendig

In conclusion, the current evidence on the effectiveness and safety of TAPE for treating symptomatic knee OA remains limited. Based on three RCTs, GAE demonstrated short-term benefits in pain reduction and improvement of knee OA severity at one-month post-procedure. However, these effects did not persist at longer follow-up periods, with no significant between-group differences observed at 4, 6, or 12 months in another study.

Evidenz unzureichend

Notably, complete embolisation of all genicular arteries appears to be associated with improved physical function and quality of life outcomes at longer follow-up, suggesting that the extent of embolisation may influence treatment efficacy. Nevertheless, no significant improvements were observed in symptoms, activities of daily living, or psychological outcomes such as anxiety and depression.

Hinweise auf bessere Wirksamkeit bei vollständiger Embolisation im Vergleich zu punktueller Embolisation

The evidence base is constrained by the small number of available RCTs, relatively small sample sizes, heterogeneity in embolic agents used, and limited follow-up durations. Furthermore, no studies investigating TAPE for shoulder OA could be identified, leaving a significant gap in the evidence.

Vergleichbarkeit der Studien eingeschränkt

aktuelle Evidenz unzureichend für GAE

Given these limitations, current evidence is insufficient to support TAPE as a standard treatment option for knee or shoulder OA. Further high-quality RCTs with larger sample sizes, longer follow-up periods, and standardised protocols are needed to establish the long-term effectiveness and safety of this intervention.

6 Evidence-based conclusions

In Table 6-1 the scheme for evidence-based conclusion is displayed and the according choice is highlighted.

Schlussfolgerung

Table 6-1: Evidence based conclusions

	1	Strong evidence for added benefit in routine use.
	2a	Evidence indicates added benefit only in specific indications.
	2b	Less robust evidence indicating an added benefit in routine use or in specific indications
X	3	No evidence or inconclusive evidence available to demonstrate an added benefit of the intervention of interest.
	4	Strong evidence indicates that intervention is ineffective and or harmful.

Reasoning:

unzureichende Evidenz für GAE als Routineeinsatz

The current evidence is not sufficient to prove that GAE provides a clinically meaningful added benefit in routine use or in specific indications. GAE may provide short-term benefit in selected patients (complete embolisation) and is safe, but it is not sufficient to prove sustained long-term effectiveness or superiority over established treatment options. New study results from larger RCTs with standardised embolic agents, specific conditions (partial/complete embolisation), prolonged blinding, and extended follow-up have the potential to considerably influence the effect estimates and clarify the technology's role in defined patient subgroups.

Re-Evaluierung in 2029

The re-evaluation is recommended in 2029.

7 References

[1] March L, Cross M, Lo C, et al. Osteoarthritis: A Serious Disease: Submitted to the US Food and Drug Administration. 2016.

[2] Dobson GP, Letson HL, Grant A, et al. Defining the osteoarthritis patient: back to the future. *Osteoarthritis Cartilage*. 2018; 26 (8): 1003-7. 10.1016/j.joca.2018.04.018.

[3] Loef M, Schoones JW, Kloppenburg M, et al. Fatty acids and osteoarthritis: different types, different effects. *Joint Bone Spine*. 2019; 86 (4): 451-8. 10.1016/j.jbspin.2018.07.005.

[4] Stewart HL, Kawcak CE. The Importance of Subchondral Bone in the Pathophysiology of Osteoarthritis. *Front Vet Sci*. 2018; 5: 178. 10.3389/fvets.2018.00178.

[5] National Institute for Health and Care Excellence (NICE). Osteoarthritis in over 16s: diagnosis and management. Guideline. 2022.

[6] Yunus MHM, Nordin A, Kamal H. Pathophysiological Perspective of Osteoarthritis. *Medicina (Kaunas)*. 2020; 56 (11). 10.3390/medicina56110614.

[7] Kobayashi T, Takagishi K, Shitara H, et al. Prevalence of and risk factors for shoulder osteoarthritis in Japanese middle-aged and elderly populations. *J Shoulder Elbow Surg*. 2014; 23 (5): 613-9. 10.1016/j.jse.2013.11.031.

[8] Bierma-Zeinstra SM, Koes BW. Risk factors and prognostic factors of hip and knee osteoarthritis. *Nat Clin Pract Rheumatol*. 2007; 3 (2): 78-85. 10.1038/ncprheum0423.

[9] Deutsche Gesellschaft für Orthopädie und Unfallchirurgie e.V. Prävention und Therapie der Gonarthrose. 2024

[10] Kellgren JH, Lawrence JS. Radiological assessment of osteo-arthrosis. *Ann Rheum Dis*. 1957; 16 (4): 494-502. 10.1136/ard.16.4.494.

[11] Bellamy N, Buchanan WW, Goldsmith CH, et al. Validation study of WOMAC: a health status instrument for measuring clinically important patient relevant outcomes to antirheumatic drug therapy in patients with osteoarthritis of the hip or knee. *J Rheumatol*. 1988; 15 (12): 1833-40.

[12] Naal FD, Impellizzeri FM, Sieverding M, et al. The 12-item Oxford Knee Score: cross-cultural adaptation into German and assessment of its psychometric properties in patients with osteoarthritis of the knee. *Osteoarthritis Cartilage*. 2009; 17 (1): 49-52. 10.1016/j.joca.2008.05.017.

[13] Insall JN, Dorr LD, Scott RD, et al. Rationale of the Knee Society clinical rating system. *Clin Orthop Relat Res*. 1989; (248): 13-4.

[14] Lequesne MG, Mery C, Samson M, et al. Indexes of severity for osteoarthritis of the hip and knee. Validation – value in comparison with other assessment tests. *Scand J Rheumatol Suppl*. 1987; 65: 85-9. 10.3109/03009748709102182.

[15] Kessler S, Lang S, Puhl W, et al. The Knee Injury and Osteoarthritis Outcome Score--a multifunctional questionnaire to measure outcome in knee arthroplasty. *Zeitschrift fur Orthopadie und ihre Grenzgebiete*. 2003; 141 (3): 277-82.

[16] Michener LA, McClure PW, Sennett BJ. American Shoulder and Elbow Surgeons Standardized Shoulder Assessment Form, patient self-report section: reliability, validity, and responsiveness. *J Shoulder Elbow Surg*. 2002; 11 (6): 587-94. 10.1067/mse.2002.127096.

[17] Constant CR, Murley AH. A clinical method of functional assessment of the shoulder. *Clin Orthop Relat Res*. 1987; (214): 160-4.

[18] Amstutz HC, Sew Hoy AL, Clarke IC. UCLA anatomic total shoulder arthroplasty. *Clin Orthop Relat Res*. 1981; (155): 7-20.

[19] Collaborators GBDO. Global, regional, and national burden of osteoarthritis, 1990-2020 and projections to 2050: a systematic analysis for the Global Burden of Disease Study 2021. *Lancet Rheumatol*. 2023; 5 (9): e508-e22. 10.1016/S2665-9913(23)00163-7.

[20] Hitzl W, Stamm T, Kloppenburg M, et al. Projected number of osteoarthritis patients in Austria for the next decades – quantifying the necessity of treatment and prevention strategies in Europe. *BMC Musculoskelet Disord*. 2022; 23 (1): 133. 10.1186/s12891-022-05091-5.

[21] Englund M. Osteoarthritis, part of life or a curable disease? A bird's-eye view. *J Intern Med*. 2023; 293 (6): 681-93. 10.1111/joim.13634.

[22] Excellence; NIfHaC. Osteoarthritis in over 16s: diagnosis and management: Evidence review for additional benefit of imaging in the diagnosis of osteoarthritis. London: National Institute for Health and Care Excellence (NICE); 2022

[23] Okuno Y, Matsumura N, Oguro S. Transcatheter arterial embolization using imipenem/cilastatin sodium for tendinopathy and enthesopathy refractory to nonsurgical management. *J Vasc Interv Radiol*. 2013; 24 (6): 787-92. 10.1016/j.jvir.2013.02.033.

[24] Little MW, Gibson M, Briggs J, et al. Genicular artEry embolizatioN in patiEnts with oSteoarthrItiS of the Knee (GENESIS) Using Permanent Microspheres: Interim Analysis. *Cardiovasc Intervent Radiol*. 2021; 44 (6): 931-40. 10.1007/s00270-020-02764-3.

[25] Bhatia A, Bhatia S. The short-to-midterm outcomes of geniculate artery embolization for mild-to-moderate osteoarthritis of the knee: a systematic review. *J Orthop*. 2023; 39: 30-41. 10.1016/j.jor.2023.03.009.

[26] Heller DB, Beggin AE, Lam AH, et al. Geniculate Artery Embolization: Role in Knee Hemarthrosis and Osteoarthritis. *Radiographics*. 2022; 42 (1): 289-301. 10.1148/rg.210159.

[27] Katoh M, Schott P, Freyhardt P, et al. [Transarterial Periarticular Embolization (TAPE): Indications and Initial Experience in Germany]. *Rofo*. 2020; 192 (11): 1046-52. 10.1055/a-1212-6149.

[28] Bannuru RR, Osani MC, Vaysbrot EE, et al. OARSI guidelines for the non-surgical management of knee, hip, and polyarticular osteoarthritis. *Osteoarthritis Cartilage*. 2019; 27 (11): 1578-89. 10.1016/j.joca.2019.06.011.

[29] McAlindon TE, Bannuru RR, Sullivan MC, et al. OARSI guidelines for the non-surgical management of knee osteoarthritis. *Osteoarthritis Cartilage*. 2014; 22 (3): 363-88. 10.1016/j.joca.2014.01.003.

[30] Mathis DT, Lohrer L, Amsler F, et al. Reasons for failure in primary total knee arthroplasty – An analysis of prospectively collected registry data. *J Orthop*. 2021; 23: 60-6. 10.1016/j.jor.2020.12.008.

[31] Sharkey PF, Lichstein PM, Shen C, et al. Why are total knee arthroplasties failing today--has anything changed after 10 years? *J Arthroplasty*. 2014; 29 (9): 1774-8. 10.1016/j.arth.2013.07.024.

[32] Goldman DT, Piechowiak R, Nissman D, et al. Current Concepts and Future Directions of Minimally Invasive Treatment for Knee Pain. *Curr Rheumatol Rep*. 2018; 20 (9): 54. 10.1007/s11926-018-0765-x.

[33] Brown JM, Vandeveer ZT, Cadoret D, et al. Genicular Artery Embolization: A Technical Review of Anatomy, Pathophysiology, Current Experiences, and Future Directions. *J Clin Med*. 2025; 14 (6). 10.3390/jcm14062106.

[34] Wang B, Liang KW, Chen CH, et al. Transcatheter Arterial Embolization for Alleviating Chronic Musculoskeletal Pain and Improving Physical Function: A Narrative Review. *Diagnostics (Basel)*. 2022; 13 (1). 10.3390/diagnostics13010134.

[35] Inui S, Yoshizawa S, Shintaku T, et al. Intra-Arterial Infusion of Imipenem/Cilastatin Sodium through a Needle Inserted into the Radial Artery as a New Treatment for Refractory Trapeziometacarpal Osteoarthritis. *J Vasc Interv Radiol*. 2021; 32 (9): 1341-7. 10.1016/j.jvir.2021.06.024.

[36] Bundesministerium für Soziales G, Pflege und Konsumentenschutz (BMSGPK). Leistungskatalog BMSGPK 2026 – Codierung ambulant. 2025.

[37] Austrian Institute for Health Technology Assessment (AIHTA). *Bewertung medizinischer Einzelleistungen – MEL 2026* [cited 28.01.2026]. Available from: https://aihta.at/page/bewertung-medizinischer-einzelleistungen-mel-2026/en.

[38] Krenn C, Wilfling D, Semlitsch T, Kern J, Goetz G. *Protocol: Transarterial periarticular embolization (TAPE) for knee and shoulder osteoarthritis* [cited 28.01.2026]. Available from: https://osf.io/7e9ah/overview.

[39] Sterne JAC, Savovic J, Page MJ, et al. RoB 2: a revised tool for assessing risk of bias in randomised trials. *BMJ*. 2019; 366: l4898. 10.1136/bmj.l4898.

[40] Larsen P, Rathleff MS, Roos EM, et al. Knee injury and osteoarthritis outcome score (KOOS) – National record-based reference values. *Knee*. 2023; 43: 144-52. 10.1016/j.knee.2023.06.004.

[41] Roos EM, Roos HP, Lohmander LS, et al. Knee Injury and Osteoarthritis Outcome Score (KOOS) – development of a self-administered outcome measure. *J Orthop Sports Phys Ther*. 1998; 28 (2): 88-96. 10.2519/jospt.1998.28.2.88.

[42] Heller GZ, Manuguerra M, Chow R. How to analyze the Visual Analogue Scale: Myths, truths and clinical relevance. *Scand J Pain*. 2016; 13: 67-75. 10.1016/j.sjpain.2016.06.012.

[43] Hawker GA, Davis AM, French MR, et al. Development and preliminary psychometric testing of a new OA pain measure--an OARSI/OMERACT initiative. *Osteoarthritis Cartilage*. 2008; 16 (4): 409-14. 10.1016/j.joca.2007.12.015.

[44] Kammin EJ. The 6-Minute Walk Test: Indications and Guidelines for Use in Outpatient Practices. *J Nurse Pract*. 2022; 18 (6): 608-10. 10.1016/j.nurpra.2022.04.013.

[45] Jones CJ, Rikli RE, Beam WC. A 30-s chair-stand test as a measure of lower body strength in community-residing older adults. *Res Q Exerc Sport*. 1999; 70 (2): 113-9. 10.1080/02701367.1999.10608028.

[46] European Comission. *Information from European Union Institutions, Bodies, Offices and Agencies* [cited 10.12.2025]. Available from: https://eur-lex.europa.eu/LexUriServ/LexUriServ.do?uri=OJ:C:2011:172:0001:0013:EN:PDF.

[47] van Zadelhoff TA, Bos PK, Moelker A, et al. Genicular artery embolisation versus sham embolisation for symptomatic osteoarthritis of the knee: a randomised controlled trial. *BMJ Open*. 2024; 14 (10): e087047. 10.1136/bmjopen-2024-087047.

[48] Landers S, Hely R, Hely A, et al. Genicular artery embolization for early-stage knee osteoarthritis: results from a triple-blind single-centre randomized controlled trial. *Bone Jt Open*. 2023; 4 (3): 158-67. 10.1302/2633-1462.43.BJO-2022-0161.R2.

[49] Bagla S, Piechowiak R, Sajan A, et al. Multicenter Randomized Sham Controlled Study of Genicular Artery Embolization for Knee Pain Secondary to Osteoarthritis. *J Vasc Interv Radiol*. 2022; 33 (1): 2-10 e2. 10.1016/j.jvir.2021.09.019.

[50] van Zadelhoff TA, Moelker A, Bierma-Zeinstra SMA, et al. Genicular artery embolization as a novel treatment for mild to moderate knee osteoarthritis: protocol design of a randomized sham-controlled clinical trial. *Trials*. 2022; 23 (1): 24. 10.1186/s13063-021-05942-x.

[51] Landers S, Hely A, Harrison B, et al. Protocol for a single-centre, parallel-arm, randomised controlled superiority trial evaluating the effects of transcatheter arterial embolisation of abnormal knee neovasculature on pain, function and quality of life in people with knee osteoarthritis. *BMJ Open*. 2017; 7 (5): e014266. 10.1136/bmjopen-2016-014266.

[52] Guyatt G, Oxman AD, Akl EA, et al. GRADE guidelines: 1. Introduction-GRADE evidence profiles and summary of findings tables. *J Clin Epidemiol*. 2011; 64 (4): 383-94. 10.1016/j.jclinepi.2010.04.026.

[53] Holtedahl R, Brox JI, Tjomsland O. Placebo effects in trials evaluating 12 selected minimally invasive interventions: a systematic review and meta-analysis. *BMJ Open*. 2015; 5 (1): e007331. 10.1136/bmjopen-2014-007331.

[54] Chlorogiannis DD, Vasilopoulou A, Konstantinidis CI, et al. Knee pain improvement after genicular artery embolization for the management of knee osteoarthritis: an updated systematic review and meta-analysis of 21 studies. *Radiologie (Heidelb)*. 2024; 64 (Suppl 1): 32-46. 10.1007/s00117-024-01388-9.

[55] Ashraf N, Tahir MJ, Arabi TZ, et al. Safety and Efficacy of Genicular Artery Embolization for Knee Joint Osteoarthritis Associated Pain: A Systematic Review. *J Endovasc Ther*. 2025: 15266028251326770. 10.1177/15266028251326770.

[56] Berreta RS, Rubin J, Manivannan A, et al. Geniculate Artery Embolization for the Treatment of Mild to Moderate Knee Osteoarthritis Improves Pain and Function at Short-Term Follow-Up With Significant Procedural Heterogeneity Described Across the Literature: A Systematic Review. *Arthroscopy*. 2025; 41 (6): 2117-33. 10.1016/j.arthro.2024.07.033.

[57] Epelboym Y, Mandell JC, Collins JE, et al. Genicular Artery Embolization as a Treatment for Osteoarthritis Related Knee Pain: A Systematic Review and Meta-analysis. *Cardiovasc Intervent Radiol*. 2023; 46 (6): 760-9. 10.1007/s00270-023-03422-0.

[58] Hernandez-Yumar A, Gonzalez-Hernandez Y, Del Pino-Sedeno T, et al. Genicular artery embolization for knee osteoarthritis: a systematic review with meta-analysis and cost-analysis. *Gac Sanit*. 2025; 39: 102459. 10.1016/j.gaceta.2025.102459.

[59] Milhem F, Takhman M, Elgendy MS, et al. Genicular artery embolization for knee osteoarthritis: A systematic review of sham-controlled randomized trials. *J Orthop*. 2025; 67: 361-8. 10.1016/j.jor.2025.07.022.

[60] Taslakian B, Miller LE, Mabud TS, et al. Genicular artery embolization for treatment of knee osteoarthritis pain: Systematic review and meta-analysis. *Osteoarthr Cartil Open*. 2023; 5 (2): 100342. 10.1016/j.ocarto.2023.100342.

[61] Kwak DH, Hofmann HL, Patel M, et al. Genicular Artery Embolization, Radiofrequency Ablation, and Corticosteroid Therapy for Knee Osteoarthritis: A Cost-Effectiveness Analysis Using Randomized Clinical Trial Data. *AJR Am J Roentgenol*. 2024; 223 (6): e2431710. 10.2214/AJR.24.31710.

[62] Whiting P, Savovic J, Higgins JPT, et al. [ROBIS: a new tool to assess risk of bias in systematic reviews was developed.]. *Recenti Prog Med*. 2018; 109 (9): 421-31. 10.1701/2990.29928.

[63] EUnetHTA Joint Action 2. *Work Package 8. HTA Core Model® version 3.0* [cited 07.01.2026]. Available from: https://www.eunethta.eu/wp-content/uploads/2018/03/HTACoreModel3.0-1.pdf.

[64] Cousins S, Blencowe NS, Tsang C, et al. Reporting of key methodological issues in placebo-controlled trials of surgery needs improvement: a systematic review. *J Clin Epidemiol*. 2020; 119: 109-16. 10.1016/j.jclinepi.2019.11.016.

[65] European Network for Health Technology Assessment (EUnetHTA). *HTA Core Model®* [cited 23.02.2026]. Available from: https://web.archive.org/web/20230323052045/https://www.eunethta.eu/.

[66] European Commission (EC). *Health technology assessment – Key documents* [cited 23.02.2026]. Available from: https://health.ec.europa.eu/health-technology-assessment/key-documents_en?f%5B0%5D=topic_topic%3A227.

Appendix

Evidence tables of individual studies included for clinical effectiveness and safety

Table A-1: Genicular artery embolisation (GAE): Results from randomised controlled trials

Author, year	van Zadelhoff 2024 [47]	Landers 2023 [48]	Bagla 2022 [49]
Country	Netherlands	Australia	USA
Sponsor	Stichting Coolsingel, COOK Medical, and Erasmus MC MRACE	Royal Australia and New Zealand College of Radiologists	University of North Carolina, Chapel Hill This study was performed under an investigational device exemption granted by the Food and Drug Administration.
Intervention/Product	GAE with 75 or 100 µm of Embozene microspheres, local anastehesia with 10 mL 2% lidocaine, insertment of a 4 Fr catheter into the common femoral artery with an anterograde approach, advancement of a multi-purpose catheter with haemostatic valve and a 1.8 Fr microcatheter	Transcatheter arterial embolisation with 0.5g imipenem and cilastatin sodium, light sedation, insertment of a 3 F introducer sheath into the femoral artery, advancement of a 2.6 F microcatheter to the genicular artery	GAE with 100 to 300-micron absorbable particles (OptiSphere), diluting 2 ml of particles in solution with 18 mL of contrast material, advancement of a 2.4-F microcatheter to the genicular arteries
Comparator	Sham embolisation	Sham embolisation	Sham embolisation
Study design	RCT (single-centre, double-blind)	RCT (single-centre, triple-blind)	RCT (multi-centre, single-blind)
Number of pts	29 vs 29	29 vs 30	14 vs 7
Inclusion criteria	■ age ≥18 years ■ knee pain for ≥6 months ■ knee pain (NRS ≥4 to ≤8) on at least half of the days in the preceding month ■ insufficient response to conservative treatment (defined as physio-therapy aimed at strengthening the lower extremities, NSAIDs, intra-articular steroid or hyaluronic acid injections and use of walking aids) for ≥6 months determined by an orthopaedic surgeon ■ Kellgren-Lawrence grade 1-3 findings on knee radiography determined by a musculoskeletal radiologist	■ 18 to 75 years of age ■ Kellgren-Lawrence grade 2 findings on knee radiography ■ moderate to severe unilateral knee pain that was resistant to at least six months of conservative treatment	■ age >40 years ■ Kellgren-Lawrence grade 1-3 findings on knee radiography ■ a score greater than 50/100 on the VAS for pain ■ pain refractory to 3 months of conservative therapies (medication, physical therapy, or intra-articular injection)
Age of patients (yrs)	59 ± 8.6 vs 57.3 ± 8.0	61.1 ± 8.0 vs 60.1 ± 7.7	63.9 ± 8.37 vs 62.9 ± 7.13
Female, n (%)	19 (65.5) vs 16 (55.2)	18 (62.1) vs 19 (63.3)	12 (86) vs 6 (43)
BMI, kg/m^2	29 (4.6) vs 31 (4.8)	30.2 (27.8 to 37.8) vs 33.6 (29.4 to 36.2)	30.8 (8.14) vs 33.4 (10.5)
Kellgren-Lawrence grade	2.4 ± 0.51 vs 2.3 ± 0.76	2 (mean values not reported)	grade 1: 3 (10.3) vs 1 (3.4) grade 2: 9 (31.0) vs 12 (41.4) grade 3: 17 (58.6) vs 16 (55.2)
Follow-up (months)	1 and 4 months	1, 6 and 12 months	1, 3 and 6 months
Loss to follow-up, n (%)	0 vs 0	0 vs 1 (3%)	3 (21%) vs 3 (43%)

Author, year	van Zadelhoff 2024 [47]	Landers 2023 [48]	Bagla 2022 [49]
Outcomes			
Efficacy			
Change in pain intensity	***KOOS pain:*** **At baseline:** 44.4 ± 15.6 vs 42.3 ± 16.5 **After 4 months (95% CI):** 21.4 (13.9 to 28.8) vs 18.4 (11.6 to 25.1) **Between-group difference at 4 months (95% CI):** 3.0 (−7.1 to 13.0), p=ns ***VAS:*** **At baseline:** 56.5 ± 17.5 vs 53.5 ± 19.9 **After 4 months (95% CI):** −22.9 (−33.07 to −12.72) vs −13.83 (−21.84 to -5.81) **Between-group difference at 4 months (95% CI):** −9.07 (−22.02 to 3.88), p=ns ***ICOAP constant:*** **At baseline:** 44.1 ± 20.1 vs 43.4 ± 20.9 **After 4 months (95% CI):** −22.07 (−30.93 to −13.21) vs −17.59 (−24.86 to −10.31) **Between-group difference at 4 months (95% CI):** −4.48 (−15.94 to 6.98), p=ns ***ICOAP intermittent:*** **At baseline:** 49.3 ± 14.9 vs 47.8 ± 20.3 **After 4 months (95% CI):** −19.68 (−27.85 to −11.51) vs −16.67 (−24.92 to −8.42) **Between-group difference at 4 months (95% CI):** −3.02 (−14.63 to 8.59), p=ns	***KOOS pain:*** **At baseline:** 47.2 (36.1 to 52.8) vs 47.2 (30.6 to 52.8) ***Partial embolisation[1]:*** **Between-group difference at 1 month (95% CI):** 0 (−13.4 to 13.4), p=nr **Between-group difference at 6 months (95% CI):** −2.6 (−21.8 to 16.7), p=nr **Between-group difference at 12 months (95% CI):** 3.0 (−18.0 to 23.9), p=ns ***Complete embolisation[2]:*** **Between-group difference at 12 months (95% CI):** 11.0 (−13.7 to 35.7), p=ns ***Global change in knee pain[3]:*** **Improved at 1 month:** 17 (58.6) vs 14 (46.7), difference by 11.9%, p=ns **Improved at 6 months:** 15 (51.7) vs 12 (40.0), difference by 11.7%, p=ns **Improved at 12 months:** 17 (58.6) vs 11 (37.9), difference by 20.7%, p=ns	***VAS:*** **At baseline:** 81.3 ± 3.1 vs 78.9 ± 3.4 **After 1 month:** 30.5 (7.4) vs 78.4 (3.6) **Between-group difference at 1 month (95% CI):** 50.1 (29.0 to 72.3), p=<0.01 **After 3 months :** 21.7 (nr) vs nr **After 6 months:** 20.3 (nr) vs nr **After 12 months:** 26.7 (nr) vs nr
Change in physical function	***KOOS sports and recreational activities:*** **At baseline:** 17.7 ± 16.7 vs 18.6 ± 16.8 **After 4 months (95% CI):** 22.32 (14.21 to 30.43) vs 10.24 (2.25 to 18.23) **Between-group difference at 4 months (95% CI):** 12.08 (0.70 to 23.45), p=0.04	***KOOS sports and recreational activities:*** **At baseline:** 20.0 (10.0 to 40.0) vs 27.5 (5.0 to 45.0) ***Partial embolisation[1]:*** **Between-group difference at 1 months (95% CI):** 0.4 (−23.2 to 23.9), p=ns **Between-group difference at 6 months (95% CI):** 4.3 (−20.1 to 28.7), p=ns	nr

Author, year	van Zadelhoff 2024 [47]	Landers 2023 [48]	Bagla 2022 [49]
Change in physical function *(continuation)*		**Between-group difference at 12 months (95% CI):** 12.5 (–15.8 to 40.8), p=ns ***6-minute-walking test[4]:*** **At baseline:** 386 (329 to 435) vs 378 (285 to 440) **Between-group difference at 1 months (95% CI):** 13 (–34 to 59), p=ns **Between-group difference at 6 months (95% CI)[1]:** –18 (–62 to 25), p=ns **Between-group difference at 12 months (95% CI)[2]:** 6 (–66 to 79), p=ns ***30-second chair stand test[5]:*** **At baseline:** 9 (8 to 11) vs 9 (7 to 12) **Between-group difference at 1 months (95% CI):** 0.9 (–0.7 to 2.4), p=ns **Between-group difference at 6 months (95% CI)[1]:** –1.0 (–3.1 to 1.1), p=ns **Between-group difference at 12 months (95% CI)[2]:** 0.8 (–2.2 to 3.7), p=ns ***Complete embolisation[2]:*** **Between-group difference at 12 months (95% CI):** 48.5 (10.5 to 86.4), p=<0.05	
Change in symptoms	***KOOS symptoms:*** **At baseline:** 50.2 ± 17.2 vs 51.0 ± 21.0 **After 4 months (95% CI):** 19.33 (11.59 to 27.08) vs 17.0 (10.26 to 23.73) **Between-group difference at 4 months (95% CI):** 2.34 (–7.92 to 12.60), p=ns	***KOOS symptoms:*** **At baseline:** 50.0 (35.7 to57.1) vs 50.0 (39.3 to 60.7) ***Partial embolisation[1]:*** **Between-group difference at 1 month (95% CI):** 2.2 (–6.9 to 11.4), p=ns **Between-group difference at 6 months (95% CI):** –3.2 (-20.7 to 14.4), p=ns **Between-group difference at 12 months (95% CI):** 9.3 (–7.2 to 25.8), p=ns ***Complete embolisation[2]:*** **Between-group difference at 12 months (95% CI):** 14.1 (–4.9 to 33.0), p=ns	***WOMAC[6]:*** **At baseline:** 64.9 ± 4.3 vs 70.9 ± 4.6 **After 1 month:** 34.7 (6.4) vs 65.9 (4.0) **Difference at 1 month between IG and CG (95% CI):** 25.2 (3.5 to 45.9), p=0.02 **After 3 months :** 19.8 (nr) vs nr **After 6 months:** 29.3 (nr) vs nr **After 12 months:** 17.9 (nr) vs nr

Author, year	van Zadelhoff 2024 [47]	Landers 2023 [48]	Bagla 2022 [49]
Change in concurrent medication and treatment	***Number of patients using concurrent medication:*** **At baseline:** 18 vs 18 **After 1 month:** 12 vs 15, p=ns **After 4 months:** 13 vs 13, p=ns	***Analgesia:*** **At baseline:** 72% vs 80%, p=ns **After 12 months:** 24% vs 48%, p=ns ***Additional treatment:*** **Physiotherapy/exercise:** 12 vs 4 **Corticosteroid injection:** 1 vs 0 **Arthroscopy**: 0 vs 1 **Knee brace:** 0 vs 1 **Knee arthroplasty:** 0 vs 1	nr
Activities of daily living	***KOOS ADL function:*** **At baseline:** 53.1 ± 15.9 vs 50.1 ± 18.0 **After 4 months (95% CI):** 21.27 (13.57 to 28.97) vs 15.75 (8.85 to 22.66) **Between-group difference at 4 months (95% CI):** 5.52 (-4.82 to 15.86), p=ns	***KOOS ADL function:*** **At baseline:** 50.0 (41.2 to 58.8) vs 53.7 (33.8 to 66.2) ***Partial embolisation[1]:*** **Between-group difference at 1 months (95% CI):** −1.5 (−18.2 to 15.3), p=ns **Between-group difference at 6 months (95% CI):** −6.1 (−23.9 to 11.6), p=ns **Between-group difference at 12 months (95% CI):** 7.4 (−9.2 to 23.9), p=ns ***Complete embolisation[2]:*** **Between-group difference at 12 months (95% CI):** 11.0 (−11.1 to 33.2), p=ns	nr
Quality of life	***EQ-5D-5L:*** **At baseline:** 0.6 ± 0.2 vs 0.6 ± 0.3 **After 4 months (95% CI):** 0.09 (−0.01 to 0.19) vs 0.11 (0.03 to 0.18) **Between-group difference at 4 months (95% CI):** −0.01 (−0.14 to 0.11), p=ns	***KOOS quality of life:*** **At baseline:** 18.8 (12.5 to 31.3) vs 37.5 (6.3 to 43.8) ***Partial embolisation[1]:*** **Between-group difference at 1 months (95% CI):** 6.3 (−5.5 to 18.0), p=ns **Between-group difference at 6 months (95% CI):** 6.3 (−11.2 to 23.7), p=ns **Between-group difference at 12 months (95% CI):** 16.7 (−0.7 to 34.0), p=ns ***Complete embolisation[2]:*** **Between-group difference at 12 months (95% CI):** 25.0 (4.9 to 45.1), p=<0.05	nr

Author, year	van Zadelhoff 2024 [47]	Landers 2023 [48]	Bagla 2022 [49]
Psychosocial outcomes	nr	***Partial embolisation[1]:*** ***Anxiety (HADS):*** **At baseline:** 6 (5 to 11) vs 6 (1 to 11) **Between-group difference at 1 months (95% CI):** −1.0 (−3.2 to 1.2), p=ns **Between-group difference at 6 months (95% CI):** 1.0 (−1.1 to 3.1), p=ns **Between-group difference at 12 months (95% CI):** 1.0 (−1.4 to 3.4), p=ns ***Depression (HADS):*** **At baseline:** 5 (3 to 10) vs 4 (2 to 7) **Between-group difference at 1 months (95% CI):** 0 (−1.9 to 1.9), p=ns **Between-group difference at 6 months (95% CI):** 0 (1.7 to 1.7), p=ns **Between-group difference at 12 months (95% CI):** −1.0 (−3.2 to 1.2), p=ns	nr
Technical success, n (%)	nr	nr	14 (100) vs 7 (100)
Safety			
Overall complications, n (%)	23 AEs vs 5 AEs[7]	4 pts/AEs vs 1 pts/AEs	5 AEs vs 6 AEs[7]
Major AE, n (%)	0 vs 0	0 vs 0	0 vs 0
Minor AE, n (%)	23 AEs vs 5 AEs[7]	4 pts/AEs vs 1 pts/AE	5 AEs vs 6 AEs[7]

Abbreviations: ADL … Activities of daily living, AE … Adverse event, CI … Confidence interval, GAE … Genicular artery embolisation, HADS … Hospital Anxiety and Depression Scale, ICOAP … Intermittent and Constant Osteoarthritis Pain, KOOS … Knee Injury and Osteoarthritis Outcome Score, NR … not reported, NRS … Numeric Rating Scale, ns … not significant, NSAIDs … Non-steroidal anti-inflammatory drugs, RCT … randomised controlled trial, VAS … Visual analogue scale, WOMAC … Western Ontario and McMaster Universities Osteoarthritis Index

Comments:

[1] *number of patients: 29 (IG) vs 30 (CG)*

[2] *number of patients: 17 (IG) vs 30 (CG)*

[3] *7-point Likert scale*

[4] *number of patients: 26 (IG) vs 26 (CG)*

[5] *number of patients: 26 (IG) vs 21 (CG)*

[6] *combined endpoint: pain, stiffness, functional limitation*

[7] *number of patients experienced AEs not reported*

Risk of bias tables and GRADE evidence profile

Internal validity of the included studies was judged by two independent researchers. In case of disagreement a third researcher was involved to solve the differences. A more detailed description of the criteria used to assess the internal validity of the individual study designs can be found in the Internal Manual of the AIHTA and in the Guidelines of EUnetHTA [63].

Table A-2: Risk of bias – outcome level (randomised studies), see [39]

Trial	Endpoints	Bias arising from the randomization process	Bias due to deviations from intended interventions	Bias due to missing outcome data	Bias in measurement of the outcome	Bias in selection of the reported result	Overall risk of bias
Bagla 2022 [49]	Change in pain intensity	Low	Low	Some concerns[1]	Low	Low	Some concerns
	Change in symptoms						
	Safety						
Landers 2023 [48]	Change in pain intensity	Low	Some concerns[3]	Low	Low	Low	Some concerns
	Change in symptoms						
	Change in physical function[2]						
	Activities of daily living						
	Quality of life						
	Psychosocial outcomes		Low				
	Change in concurrent medication intake and treatment						
	Safety						
Van Zadelhoff 2024 [47]	Change in pain intensity	Low	Low	Low	Low	Low	Low
	Change in symptoms						
	Change in physical function						
	Activities of daily living						
	Quality of life						
	Change in concurrent medication intake and treatment						
	Safety						

Comments: [1] *risk of exaggeration of treatment effects as patients in the sham group did not show improvement and were crossed over to GAE after one month*

[2] *including objective (6 minute walk distance test, 30-second chair stand test) and subjective (self-assessed questionnaire) measurements*

[3] *subgroup-analysis (complete vs. sham embolization) was defined post-randomization based on the technical success of the intervention*

Table A-3: Evidence profile: efficacy and safety of GAE in patients with symptomatic knee OA

Quality assessment							Summary of findings				
							Number of patients		Effect		Certainty of evidence
№ of studies	Study design	Risk of bias	Inconsistency	Indirectness	Imprecision	Other considerations	intervention	comparison	Relative (95% CI)	Absolute (95% CI)	
Change in pain intensity											
3 [47-49]	RCT	Not serious	Serious[a]	Not serious	Serious[b]	None	72	66	-	KOOS pain: FU 4 and 12 months: NS FU 1 and 6 months: NR VAS: FU 1 month: 50.1 (29.0 to 72.3), p=<0.01 FU 4 months: NS ICOAP constant + intermittent: FU 4 months: NS	⨁⨁◯◯ low
Change in physical function											
2 [47, 48]	RCT	Not serious	Not serious	Not serious	Serious[c]	None	58	59	-	KOOS sports and recreational activities: FU 1, 6 and 12 months: NS FU 4 months: 12.08 (0.70 to 23.45), p=0.04 Δ 6MWT: FU 1, 6 and 12 months: NS Δ 30-sec CST: FU 1, 6 and 12 months: NS	⨁⨁⨁◯ moderate
Change in symptoms											
3 [47-49]	RCT	Not serious	Serious[d]	Not serious	Serious[b]	None	72	66	-	KOOS symptoms: FU 1, 4, 6 and 12 months: NS WOMAC: FU 1 month: 25.2 (3.5 to 45.9), p=0.02	⨁⨁◯◯ low
Activities of daily living											
2 [47, 48]	RCT	Not serious	Not serious	Not serious	Serious[c]	None	58	59	-	No statistically significnat improvement of ADLs after 1, 4, 6 and 12 months FU in both studies.	⨁⨁⨁◯ moderate
Health-related quality of life											
2 [47, 48]	RCT	Not serious	Not serious	Not serious	Serious[c]	None	58	59	-	No statistically significant improvement of HrQoL in patients with partial embolisation after 1, 4, 6 and 12 months FU. HrQoL statistically significant better in patients with complete embolisation after 12 months FU (25.0 (4.9 to 45.1), p=<0.05).	⨁⨁⨁◯ moderate

Quality assessment							Summary of findings				
№ of studies	Study design	Risk of bias	Inconsistency	Indirectness	Imprecision	Other considerations	Number of patients		Effect		Certainty of evidence
							intervention	comparison	Relative (95% CI)	Absolute (95% CI)	
Anxiety											
1 [48]	RCT	Not serious	Not serious	Not serious	Serious[e]	None	29	30	-	FU 1 month: -1.0 (-3.2 to 1.2), p=ns FU 6 months: 1.0 (-1.1 to 3.1), p=ns FU 12 months: 1.0 (-1.4 to 3.4), p=ns	⨁⨁⨁◯ moderate
Depression											
1 [48]	RCT	Not serious	Not serious	Not serious	Serious[e]	None	29	30	-	FU 1 month: 0 (-1.9 to 1.9), p=ns FU 6 months: 0 (1.7 to 1.7), p=ns FU 12 months: -1.0 (-3.2 to 1.2), p=ns	⨁⨁⨁◯ moderate
Change in concurrent medication intake and treatment											
2 [47, 48]	RCT	Not serious	Not serious	Not serious	Serious[c]	None	58	59	-	No statistically significant difference of changes in concurrent medication intake and treatment between IG and CG in both studies.	⨁⨁⨁◯ moderate
Adverse events											
3 [47-49]	RCT	Not serious	Not serious	Not serious	Serious[b]	None	72	66	-	32 vs 12 AEs reported in total, number of patients experienced AEs not reported	⨁⨁⨁◯ moderate
Serious adverse events											
3 [47-49]	RCT	Not serious	Not serious	Not serious	Serious[b]	None	72	66	-	No SAEs reported in any of the studies.	⨁⨁⨁◯ moderate

Abbreviations: 6MWT … 6 minute walking test; 30-sec CST … 30-second chair stand test; ADLs … Activities of daily living; AEs … Adverse events; CG … control group; CI … Confidence interval; FU … follow-up; GAE … Genicular artery embolisation; HrQoL … Health related quality of life; IG … intervention group; KOOS … Knee Injury and Osteoarthritis Outcome Score; NS … not significant; OA … Osteoarthritis; RCT … Randomised controlled trial; SAEs … Serious adverse events; VAS … Visual Analogue Scale, WOMAC … Western Ontario and McMaster Universities Osteoarthritis Index

Comments:

[a] *inconsistent results reported after one month, different embolic agents used (embozene microspheres vs imipenem/cilastatin vs absorbable particles), different outcome measurement scales used (KOOS, VAS),*

[b] *Low number of RCTs (n=3) and small sample size (n=138)*

[c] *Low number of RCTs (n=2) and small sample size (n=117)*

[d] *Inconsistent results reported after 1 month, different outcome measurement scales used (KOOS, WOMAC), different embolic agents used (embozene microspheres, imipenem/cilastatin),*

[e] *Only one RCT with small sample size (n=59)*

Applicability table

Table A-4: Summary table characterising the applicability of a body of studies

Domain	Description of applicability of evidence
Population	All studies investigated patients with indication for symptomatic knee OA. The included study populations largely represent late middle age with mean ages ranging from 57 to 64 years and standard deviations of approximately eight years. Included populations represented moderate to severe knee OA.
Intervention	All studies investigated the effectiveness of GAE, a minimally invasive, non-surgical intervention. The studies investigated GAE with Embozene microspheres (75/100µm), imipenem and cilastatin sodium in contrast (0.5g) or micron absorbable particles (100-300µm). All GAEs were performed by interventional radiologists with several years of experience performing embolisation procedures. GAE is utilized as a treatment alternative for patients with knee osteoarthritis who have failed conservative therapy (e.g., physiotherapy/exercise, anti-inflammatory medications, or intra-articular injections) and who are ineligible for or unwilling to undergo total knee replacement surgery. It is hypothesized that reducing blood flow to the hypervascularized synovium provides immediate and long-term pain relief.
Comparators	All studies investigated a sham embolisation as the comparator. In these control groups, patients typically underwent the same preparation, catheterization, and angiography, but without the injection of embolic material. A sham procedure represents the methodological gold standard for evaluating treatment efficacy, especially for subjective outcomes, by optimizing blinding of all stakeholders and thereby minimizing bias [64].
Outcomes	The primary outcome in the studies were the reduction of knee pain intensity and the reduction of knee OA severity. Secondary outcomes comprised changes in physical function, symptoms, activities of daily living, and health-related quality of life. Furthermore, psychological factors (anxiety, depression) and the reduction in concurrent medication usage and treatment were reported.
Setting	In all studies, the intervention was performed in a clinical setting, performed in the Netherlands, in the USA, and in Australia. The applicability of the results is unlikely to be limited by geographic fators. The results are applicable to the Austrian population.

List of ongoing randomised controlled trials

Table A-5: List of ongoing randomised controlled trials of GAE for knee

Identifier/ Trial name	Patient population	No of patients (planned)	Intervention	Comparison	Primary Outcome	Estimated study completion date	Sponsor
ISRCTN15723381	■ Participants aged 45 years or above ■ Grade 3 knee OA on X-ray as per Kellgren-Lawrence (KL) Grading Scale ■ Knee pain for at least 3 months resistant to conservative treatment ■ Be able to lie flat for at least 6 hours-this will be assessed by asking how participants sleep (bed, chair recumbent, semi-recumbent) and assessing what prevents them from lying flat overnight (breathlessness, back pain, etc)	74	GAE	Sham embolisation	KOOS, VAS, analgesia diary	2024-01-01[1]	University of Reading
NCT03460665	■ An effective contraceptive system for women of childbearing age, a pregnancy test will be offered to these women in the preoperative assessment. ■ Obtaining the signature of the consent to participate in the study ■ Kellgren-Lawrence (KL) grade 2-3 assessed by routine weight-bearing knee radiographs on the most affected knee in bilateral cases ■ Pain with EVA ≥ 50 mm evolving for at least 3 months despite the start of a well-conducted medical treatment according to current recommendations including analgesics, NSAID, intra-articular injections, rehabilitation and weight loss ■ No surgical indication retained	18	GAE	Sham embolisation	Pain (VAS)	2025-01-29[1]	Centre Hospitalier Universitaire de Nice
SLCTR/2024/001	■ Males and females with an age above 30 years ■ Kelgren-Lawrence (KL) radiographic grading system – grade 3 and 4 knee osteoarthritis • Primary knee OA ■ Knee pain (>6 on visual analog scale) on at least half of the days in the preceding month at the time of inclusion ■ Registered patient in rheumatology clinic with at least 6 months of standard medical treatments	66	GAE	Standard care	Pain (VAS)	2025-05-23[1]	H. K. Rumesh Priyadarshana
NCT04456569	■ Between 40-70 years of age. ■ Unilaterally dominant symptomatic OA (bilateral radiographic OA will not exclude). ■ Symptomatically refractory of at least 3 months of medical and/or rehabilitation measures (anti-inflammatory drugs, and/or physical therapy, and/or strength conditioning, and/or intra-articular injections of the affected knee in the last 3 months). ■ Kellgren-Lawrence grade 1, 2, or 3 on radiograph of the knee ■ Willing to comply with the protocol requirements and willing to undergo non- contrast MRI during screening and at 12 months.	20	GAE	Standard care	Safety	2026-02-01	University of Minnesota

Identifier/ Trial name	Patient population	No of patients (planned)	Intervention	Comparison	Primary Outcome	Estimated study completion date	Sponsor
NCT04456569 *(continuation)*	■ Willing to comply with regular follow up during the 12 month follow-up period. ■ Not a current candidate for partial or total knee arthroplasty. ■ WOMAC Score >=6 in at least 2 categories.						
NCT06859164	■ Patients aged 40-80 ■ Bilateral or unilateral knee pain attributed to osteoarthritis ■ Grade 2-4 osteoarthritis on standing weight-bearing knee radiographs per the Kellgren-Lawrence grading scale ■ Knee pain > 6 months, refractory to conservative non-operative management, and scored ≥ 4 on Visual Analog Scale (VAS) (e.g., rest, activity modification, weight control, bracing, supervised physical therapy, nonsteroidal anti-inflammatory drugs (NSAIDs), acetaminophen, oral opiates, intra-articular hyaluronic acid, PRP, stem cells, and/or oral/injectable corticosteroids) ■ Refusal of intra-articular corticosteroid injection	50	GAE	Sham embolisation	Reduction in KOOS pain	2026-11-30	University of Chicago
NCT06872567	■ Patient has localised knee pain[2] ■ Must be an appropriate candidate for arterial vascular access procedure	126	GAE	Sham embolisation	Pain, stiffness, activites of daily living (WOMAC)	2026-12	North American Science Associates Ltd.
NCT06166628	■ Age > 40 years ■ Knee pain due to osteoarthritis for at least 6 months ■ Pain refractory to conservative therapies (oral medication, or physical therapy, or activity modification) for at least 3 months with a desire for TKA ■ Candidate for TKA at Hotel Dieu Hospital Site ■ Able to comply with all treatments and protocol follow-up visits	150	GAE	Sham embolisation	Pain, function	2026-12-31	David Clinkard
NCT06550024	■ Clinical diagnosis of knee OA, and ■ Moderate to severe knee pain (WOMAC Pain ≥ 10), and ■ Pain refractory to at least 3 months of conservative therapies (anti-inflammatory drugs, or physical therapy, or intra-articular injections), and ■ Kellgren-Lawrence grade 1, 2 or 3 on radiograph of the knee, and ■ Age ≥ 40 years and < 80 years, and ■ Able to comply with all treatments and follow-up visits.	89	GAE	Sham embolisation	Pain (WOMAC, NRS), freedom from treatment-related serious adverse events	2027-04	CrannMed
NCT05818150	■ Age ≥21 years ■ Mild to severe knee pain, defined as a WOMAC Pain score of ≥8 out of 20 (in the target knee) ■ Pain refractory to conservative therapies for at least 90 days prior to enrollment/randomization. ■ Kellgren-Lawrence grade 1, 2, 3 or 4	264	GAE	Sham embolisation	Pain (WOMAC), freedom from treatment-related safety events	2027-10	Merit Medical Systems, Inc.

Identifier/ Trial name	Patient population	No of patients (planned)	Intervention	Comparison	Primary Outcome	Estimated study completion date	Sponsor
NCT04682652	■ Provided informed consent ■ Age ≥ 40 years and less than 80 years ■ Ineligibility for or refusal of surgical management ■ Moderate-severe knee pain as determined by visual analog scale > 5 out of 10 ■ Osteoarthritis based on X-ray. Kellgren-Lawrence score > 2 based on radiograph completed within 3 months of procedure date. ■ Resistant/failed conservative treatment (e.g. NSAIDS/physical therapy/steroid joint injection/hyaluronic acid joint injection) for at least 3 months ■ Able to comply with all treatments and protocol follow-up visits	100	GAE	Observation (counseling on conservative management with a referral or prescription for physical therapy)	Change in clinical response (WOMAC)	2027-10-01	University of California, Los Angeles
ISRCTN50216144	■ Diagnosis of painful knee OA ■ Radiographic evidence of OA (KL 2-4) ■ Previously treated with NICE non-operative intervention, as determined by the treating clinician ■ Moderate/severe pain (to be confirmed when completing the baseline questionnaire ahead of the procedure measured by the pain Visual Analogue Scale [VAS] score) (35-74 moderate, 75-100 severe) ■ Not listed for or being considered as a candidate for joint replacement surgery ■ Aged 18 years or above ■ Knee hypervascularity suitable for embolisation (to be confirmed with an angiogram during the study procedure)	216	GAE	Sham embolisation	Pain (VAS)	2027-12-31	University of Oxford
NCT05423587	■ Participant is willing and able to give informed consent for participation in the study. ■ Participants aged 45 years or above. ■ Grade 1-3 knee OA on X-ray as per Kellgren-Lawrence Grading Scale ■ Knee pain for at least 3 months resistant to conservative non-surgical treatment (e.g., physiotherapy, steroid injections, weight loss programs, PRP (platelet-rich plasma) injections) ■ Be able to lie flat for at least 6 hours-this will be assessed by asking how participants sleep (bed, chair recumbent, semi-recumbent) and assessing what prevents them from lying flat overnight (breathlessness, back pain, etc) ■ Minimum score of 50 on baseline 0-100 VAS	110	GAE	Sham embolisation	Pain, symptoms, activities of daily living, quality of life	2028-06-30	Varian, a Siemens Healthineers Company

Identifier/ Trial name	Patient population	No of patients (planned)	Intervention	Comparison	Primary Outcome	Estimated study completion date	Sponsor
NCT06497140	■ Diagnosis of primary KOA according to the classification of the American College of Rheumatology (ACR) (5) ■ Radiographic Kellgren and Lawrence score ≥ 2 (6) ■ VAS pain score ≥ 40 mm (scale 0-100 mm) ■ Previous intra-articular injection in the target knee ■ Patient not eligible to knee surgery ■ For woman of childbearing potential: negative bêta-HCG before randomization ■ Social security affiliation	130	GAE	Sham embolisation	Pain (VAS)	2028-10-01	Assistance Publique – Hôpitaux de Paris
ACTRN12622001157763	■ >40 years of age. ■ Grade 2 and 3 knee Osteoarthritis on plain radiographs (Kellgren-lawrence scale). ■ Knee pain for 6 months or more, moderate to severe knee pain (VAS >50mm). ■ Pain refractory to conservative management for at least 3 months.	54	GAE	Sham embolisation	safety, efficacy, pain, analgesia usage	nr	Dr Yehia El Hgar, Liverpool Hospital

Comments:

[1] *no results published*

[2] *unclear, if participants have diagnosis of knee OA*

Research questions

Table A-6: Health problem and Current Use

Element ID	Research question
A0001	For which health conditions, and for what purposes is the technology used?
A0002	What is the disease or health condition in the scope of this assessment?
A0003	What are the known risk factors for the disease or health condition?
A0004	What is the natural course of the disease or health condition?
A0005	What is the burden of disease for the patients with the disease or health condition?
A0006	What are the consequences of the disease or health condition for the society?
A0024	How is the disease or health condition currently diagnosed according to published guidelines and in practice?
A0025	How is the disease or health condition currently managed according to published guidelines and in practice?
A0007	What is the target population in this assessment?
A0023	How many people belong to the target population?
A0011	How much are the technologies utilised?

Table A-7: Description of the technology

Element ID	Research question
B0001	What is the technology and the comparator(s)?
A0020	For which indications has the technology received marketing authorisation or CE marking?
B0002	What is the claimed benefit of the technology in relation to the comparators?
B0003	What is the phase of development and implementation of the technology and the comparator(s)?
B0004	Who administers the technology and the comparators and in what context and level of care are they provided?
B0008	What kind of special premises are needed to use the technology and the comparator(s)?
B0009	What supplies are needed to use the technology and the comparator(s)?
A0021	What is the reimbursement status of the technology?

Table A-8: Clinical Effectiveness

Element ID	Research question
D0005	How does the technology affect symptoms and findings (severity, frequency) of the disease or health condition?
D0006	How does the technology affect progression (or recurrence) of the disease or health condition?
D0011	What is the effect of the technology on patients' body functions?
D0016	How does the use of technology affect activities of daily living?
D0012	What is the effect of the technology on generic health-related quality of life?
D0013	What is the effect of the technology on disease-specific quality of life?

Table A-9: Safety

Element ID	Research question
C0008	How safe is the technology in comparison to the comparator(s)?
C0002	Are the harms related to dosage or frequency of applying the technology?
C0004	How does the frequency or severity of harms change over time or in different settings?
C0005	What are the susceptible patient groups that are more likely to be harmed through the use of the technology?
C0007	Are the technology and comparator(s) associated with user-dependent harms?

Literature search strategies

Search strategy for Medline via Ovid

Search Name: Ovid MEDLINE(R) ALL <1946 to Noevember 18, 2025>	
Search date: 19.11.2025	
ID	Search
#1	(*arthr*) (Word variations have been searched)
#2	(knee*) (Word variations have been searched)
#3	#1 OR #2
#4	MeSH descriptor: [Osteoarthritis, Knee] explode all trees
#5	(*arthr* NEAR/3 knee*) (Word variations have been searched)
#6	#4 OR #5
#7	(osteo*arthros*) (Word variations have been searched)
#8	(shoulder*) (Word variations have been searched)
#9	(glenohumeral*) (Word variations have been searched)
#10	gleno-humeral*
#11	#8 OR #9 OR #10
#12	#1 AND #11
#13	(frozen NEXT shoulder*) (Word variations have been searched)
#14	(adhesi* NEXT capsulit*) (Word variations have been searched)
#15	#12 OR #13 OR #14
#16	#6 OR #15
#17	(embolisation) (Word variations have been searched)
#18	MeSH descriptor: [Embolisation, Therapeutic] explode all trees
#19	#17 OR #18
#20	(*arteri*) (Word variations have been searched)
#21	#19 AND #20
#22	(percutaneous) (Word variations have been searched)
#23	(genicular*) (Word variations have been searched)
#24	(*catheter*) (Word variations have been searched)
#25	(endovascular) (Word variations have been searched)
#26	#20 OR #22 OR #23 OR #24 OR #25
#27	#19 AND #26
#28	(genicular NEXT arter* NEXT embolization) (Word variations have been searched)
#29	(GAE):ti,ab,kw
#30	((transarter* OR trans-arter*) NEXT embolization) (Word variations have been searched)
#31	(TAE):ti,ab,kw
#32	(TAPE):ti,ab,kw
#33	((transcatheter* OR trans-catheter*) NEXT arter* NEXT emboli*) (Word variations have been searched)
#34	#27 OR #28 OR #29 OR #30 OR #31 OR #33
#35	#16 AND #34
#36	English:la
#37	German:la
#38	#36 OR #37
#39	#35 AND #38
#40	(conference proceeding):pt
#41	(abstract):so
#42	(clinicaltrials OR trialsearch OR ANZCTR OR ensaiosclinicos OR Actrn OR chictr OR cris OR ctri OR registroclinico OR clinicaltrialsregister OR DRKS OR IRCT OR Isrctn OR rctportal OR JapicCTI OR JMACCT OR jRCT OR JPRN OR Nct OR UMIN OR trialregister OR PACTR OR R.B.R.OR REPEC OR SLCTR OR Tcr)
#43	#39 NOT #42
Total hits: 628	

HTA Austria
Austrian Institute for
Health Technology Assessment
GmbH