ISRCTN50216144 https://doi.org/10.1186/ISRCTN50216144

Genicular embolisation for knee osteoarthritis

Submission date
17/06/2025

Recruitment status
Recruiting

Registration date
09/07/2025

Overall study status
Ongoing

Last Edited
14/07/2025

Condition category
Musculoskeletal Diseases

[X] Prospectively registered
[_] Protocol
[_] Statistical analysis plan
[_] Results
[_] Individual participant data
[X] Record updated in last year

Plain English summary of protocol

Background and study aims
This study is looking at whether a new treatment called genicular artery embolisation (GAE) could be a helpful option for people with ongoing pain from knee osteoarthritis. Knee osteoarthritis is a painful condition. In the early stages, patients often benefit from lifestyle changes and exercises. When the knee becomes very damaged, they may require a knee replacement surgery to alleviate the pain and improve symptoms. In between the early and advanced stages, pain can become a major problem. A new treatment has been developed which aims to relieve pain in the knee by blocking (embolisation) small extra blood vessels around the knee. Early studies seem to show some benefit, but a larger study is needed to see if the treatment is effective at reducing pain. If it works, it could help a lot of people with knee osteoarthritis who are in a “treatment gap” between simple care and complex surgery.

Who can participate?
Adult patients with diagnosed painful knee osteoarthritis who have presented to secondary (hospital) care and previously tried existing treatments

What does the study involve?
Participants will be randomly assigned to either receive the active treatment (GAE), which uses microbeads to block off extra blood vessels in the knee, or a very similar placebo where only salt water is injected. Participants will not be aware what treatment they are undergoing. Participants will also have one or two MRI scans and will be asked to complete questionnaires assessing pain and function up to 12 months later.

What are the possible benefits and risks of participating?
Participants' knee pain may or may not improve following the procedure. With all medical procedures, there is a small risk of problems, which will be assessed by treating clinicians and discussed with participants.

Where is the study run from?
University of Oxford (UK)

When is the study starting and how long is it expected to run for?
May 2024 to December 2027

Who is funding the study?
The National Institute of Health Research (NIHR), Efficacy and Mechanism Evaluation (EME) programme (UK)

Who is the main contact?
Dr Anjali Shah, geko@ndorms.ox.ac.uk

Study website
https://geko.octru.ox.ac.uk/

Contact information

Type(s)
Scientific

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Additional identifiers

EudraCT/CTIS number
Nil known

IRAS number
324901

ClinicalTrials.gov number
Nil known

Secondary identifying numbers
CPMS 68970, Grant Code: NIHR134096

Study information

Scientific Title
Genicular artery embolisation for the symptomatic treatment of knee osteoarthritis refractory to conservative management (GEKO)

Acronym
GEKO

Study objectives
To determine, in patients with painful knee osteoarthritis (OA), if genicular artery embolisation (GAE) is effective at reducing pain at 6 months post-randomisation, compared to a placebo intervention.

Ethics approval required
Old ethics approval format

Ethics approval(s)
Approved 09/07/2025, Health and Social Care Research Ethics Committee A (HSC REC A; Office for Research Ethics Committees Northern Ireland (ORECNI), Business Services Organisation, Northern Ireland; +44 (0)28 95 361404; reca@hscni.net) ref: 25/NI/0081

Study design
Randomized; Interventional; Design type: Treatment, Imaging, Other

Primary study design
Interventional

Secondary study design
Randomised controlled trial

Study setting(s)
Hospital

Study type(s)
Treatment

Participant information sheet
Not available in web format, please use the contact details to request a patient information sheet

Health condition(s) or problem(s) studied
Knee osteoarthritis

Interventions
The study will be a multi-centre two-arm randomised controlled trial with 1:1 allocation, comparing the clinical efficacy of genicular artery embolisation with a placebo procedure. Participants and follow-up assessors will be blinded to the randomisation allocation.

Participants will be recruited from knee orthopaedic clinics. They will have the opportunity at their appointment to ask any questions they have about the study.

Screening forms will be completed at each site. These will detail any reasons for exclusion and non-participation. On the day of the procedure, but prior to the procedure, possible eligibility will be re-confirmed and participants will complete a baseline questionnaire.

Completing the baseline questionnaire will confirm whether the participant has moderate /severe knee pain measured by the pain Visual Analogue Scale (VAS) score (35-74 moderate, 75-100 severe) and therefore eligible for the study. Those who do not meet the eligibility criterion of moderate/severe pain would not undergo the procedure as pain is the main indication for treatment, and they would not proceed with the study.

During the procedure, a medical image (angiogram) will be taken to check if the patient does have knee hypervascularity, and therefore, to confirm they are eligible for the study and can be randomised to the study. If the participant does not have knee hypervascularity, then they will not be able to have the intervention and they will not be randomised to the study. For these ineligible patients, a complications check will be made at 6 weeks after the procedure.

Participants with knee hypervascularity will be randomised during the procedure to receive one of two possible interventions. Randomisation will function via the REDCap database online system. Group 1 will receive genicular artery embolisation and group 2 will have a placebo procedure with no embolisation. Participants will be blinded to their allocation.

The participants will need a day at the hospital for the procedure and usual pre- and post-procedure care. Most participants will be able to go home on the same day if all goes well.

Study follow-up consists of participant questionnaires at 6 weeks, 3 months, 6 months and 12 months post randomisation, and a contrast MRI scan at 3 months for a subgroup of 90 participants, and a standard MRI scan at 6 months for all participants. The questionnaires include a validated visual analogue scale (VAS), Knee Injury Osteoarthritis Outcome Score (KOOS), painDETECT, and EQ-5D-5L validated questionnaires, and bespoke complications and health research use questionnaires.

There will be a check for complications for all patients randomised in the study on the procedure day and up to 12 months post-procedure.

During the study we will consent participants for long-term follow-up and access to their routine NHS records (HES data linkage). This will allow for assessment of any long-term effects. This further follow-up would be subject to the receipt of additional funding.

There is an embedded 8-month pilot phase within the study to assess: recruitment rate; ability to maintain assessor and patient blinding; adherence to the randomised procedure and early retention rates. In addition, we have embedded secondary mechanistic outcomes, taking advantage of the controlled placebo trial methodology to investigate the link between synovitis, hypervascularity and knee pain in osteoarthritis using standard and contrast-enhanced MRI and angiograms.

Radiologists within the central team will review the first three patients who have a procedure with each site radiologist to assess the number of patients found to not have knee hypervascularity, and to assess whether the procedure went smoothly, as reported by the radiologists performing the procedure.

Intervention Type
Procedure/Surgery

Primary outcome measure
Pain measured using the visual analogue scale (VAS) at 6 months follow-up

Secondary outcome measures
Measured at baseline, 6 weeks, 3, 6 and 12 months:
1. Pain measured using VAS
2. Knee function measured using the Knee Injury and Osteoarthritis Outcome Score (KOOS)
3. Pain measured using painDETECT
4. Health-related quality of life measured using EQ-5D-5L
5. Health resource use measured using a bespoke questionnaire

Overall study start date
01/05/2024

Completion date
31/12/2027

Eligibility

Key inclusion criteria
1. Diagnosis of painful knee OA
2. Radiographic evidence of OA (KL 2-4)
3. Previously treated with NICE non-operative intervention, as determined by the treating clinician
4. 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)
5. Not listed for or being considered as a candidate for joint replacement surgery
6. Aged 18 years or above
7. Knee hypervascularity suitable for embolisation (to be confirmed with an angiogram during the study procedure)
8. Patient willing and able to give informed consent

Participant type(s)
Patient

Age group
Adult

Lower age limit
18 Years

Sex
Both

Target number of participants
Planned Sample Size: 216; UK Sample Size: 216

Key exclusion criteria
1. Patient previously participated in the GEKO trial (only one knee can be entered into the trial)
2. Received a steroid injection in the study knee in the past 6 weeks, or is scheduled to have a steroid injection prior to the study procedure
3. Infection or malignancy around the knee
4. Inflammatory arthropathy
5. History of acute injury to the knee (within 6 months)
6. Surgery to the involved knee in the past 6 months
7. Previous knee replacement (partial or total) in either limb
8. Severe allergic reaction to radiological contrast media, including iodine-based CT-contrast or Gadolinium-based MRI contrast
9. Objection (religious or personal) to the use of medical materials made from pigs
10. Allergy to gelatine from pigs (which is within the micro-beads used in the intervention)
11. Known significant renal impairment
12. Peripheral artery disease of the affected leg
13. Pregnant or lactating
14. Hepatic impairment
15. Clotting abnormality
16. Osteonecrosis

Date of first enrolment
31/07/2025

Date of final enrolment
30/06/2026

Locations

Countries of recruitment
England

Scotland

United Kingdom

Wales

Study participating centre
Oxford University Hospitals NHS Foundation Trust
John Radcliffe Hospital
Headley Way
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Study participating centre
Royal Cornwall Hospitals NHS Trust
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Study participating centre
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Study participating centre

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Study participating centre
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Study participating centre
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Study participating centre
Hull University Teaching Hospitals NHS Trust
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Study participating centre
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Study participating centre
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Study participating centre
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Sponsor type
University/education

Website
https://www.ox.ac.uk

ROR
https://ror.org/052gg0110

Funder(s)

Funder type
Government

Funder Name
National Institute for Health and Care Research

Alternative Name(s)
National Institute for Health Research, NIHR Research, NIHRresearch, NIHR - National Institute for Health Research, NIHR (The National Institute for Health and Care Research), NIHR

Funding Body Type
Government organisation

Funding Body Subtype
National government

Location
United Kingdom

Results and Publications

Publication and dissemination plan
Planned publication in a high-impact peer-reviewed journal

Intention to publish date
31/12/2028

Individual participant data (IPD) sharing plan
The datasets generated during and/or analysed during the current study will be available upon request from the Chief Investigator.

IPD sharing plan summary
Data sharing statement to be made available at a later date