

# Genicular embolisation for knee osteoarthritis

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<b>Last Edited</b> 14/07/2025	<b>Condition category</b> Musculoskeletal Diseases	<input type="checkbox"/> Individual participant data <input checked="" type="checkbox"/> 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

## Contact information

### Type(s)

Scientific

### Contact name

Dr Anjali Shah

### Contact details

Surgical Intervention Trials Unit

Botnar Research Centre

Nuffield Department of Orthopaedics Rheumatology and Musculoskeletal Sciences (NDORMS)

University of Oxford

Windmill Road

Headington

Oxford

United Kingdom

OX3 7LD

+44 (0)1865 613460

anjali.shah@ndorms.ox.ac.uk

### Type(s)

Principal investigator

### Contact name

Prof Andrew Price

### Contact details

Botnar Research Centre

Nuffield Department of Orthopaedics Rheumatology and Musculoskeletal Sciences (NDORMS)

University of Oxford

Windmill Road

Headington

Oxford

United Kingdom

OX3 7LD

+44 (0)1865 223421

andrew.price@ndorms.ox.ac.uk

### Type(s)

Principal investigator

### Contact name

Dr Raman Uberoi

### **Contact details**

John Radcliffe Hospital  
Headley Way  
Headington  
Oxford  
United Kingdom  
OX3 9DU  
+44 (0)1865 221497  
raman.uberoi@ouh.nhs.uk

## **Additional identifiers**

### **Integrated Research Application System (IRAS)**

324901

### **Central Portfolio Management System (CPMS)**

68970

### **National Institute for Health and Care Research (NIHR)**

134096

### **Protocol serial number**

Grant Code:

## **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

## **Study type(s)**

Treatment

## **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(s)**

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

### **Key secondary outcome(s)**

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

### **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

## Healthy volunteers allowed

No

## Age group

Adult

## Lower age limit

18 years

## Sex

All

## 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

United Kingdom

England

Scotland

Wales

**Study participating centre**

**Oxford University Hospitals NHS Foundation Trust**

John Radcliffe Hospital

Headley Way

Headington

Oxford

United Kingdom

OX3 9DU

**Study participating centre**

**Royal Cornwall Hospitals NHS Trust**

Royal Cornwall Hospital

Treliske

Truro

United Kingdom

TR1 3LJ

**Study participating centre**

**Aneurin Bevan University Lhb**

Headquarters - St Cadoc's Hospital

Lodge Road

Caerleon

Newport

United Kingdom

NP18 3XQ

**Study participating centre**

**North Bristol NHS Trust**

Southmead Hospital

Southmead Road

Westbury-on-trym

Bristol

United Kingdom

BS10 5NB

**Study participating centre**

**Imperial College Healthcare NHS Trust**

The Bays

St Marys Hospital

South Wharf Road

London

United Kingdom

W2 1BL

**Study participating centre**  
**University Hospitals Plymouth NHS Trust**  
Derriford Hospital  
Derriford Road  
Derriford  
Plymouth  
United Kingdom  
PL6 8DH

**Study participating centre**  
**Liverpool University Hospitals NHS Foundation Trust**  
Royal Liverpool University Hospital  
Prescot Street  
Liverpool  
United Kingdom  
L7 8XP

**Study participating centre**  
**Hull University Teaching Hospitals NHS Trust**  
Hull Royal Infirmary  
Anlaby Road  
Hull  
United Kingdom  
HU3 2JZ

**Study participating centre**  
**Guy's & St Thomas Hospital**  
Westminster Bridge Road  
London  
United Kingdom  
SE1 7EH

**Study participating centre**  
**University Hospitals Coventry and Warwickshire NHS Trust**  
Walsgrave General Hospital  
Clifford Bridge Road  
Coventry  
United Kingdom  
CV2 2DX

**Study participating centre**  
**Cambridge University Hospitals NHS Foundation Trust**  
Cambridge Biomedical Campus  
Hills Road  
Cambridge  
United Kingdom  
CB2 0QQ

**Study participating centre**  
**Barts Health NHS Trust**  
The Royal London Hospital  
80 Newark Street  
London  
United Kingdom  
E1 2ES

**Study participating centre**  
**Cardiff & Vale University Lhb**  
Woodland House  
Maes-y-coed Road  
Cardiff  
United Kingdom  
CF14 4HH

## **Sponsor information**

**Organisation**  
University of Oxford

**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

### 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

### Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
<a href="#">Study website</a>	Study website	11/11/2025	11/11/2025	No	Yes