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Genicular artery embolisation for osteoarthritis of the knee in Wales

Submission date
14/01/2023

Recruitment status
No longer recruiting

Registration date
18/05/2023

Overall study status
Completed

Last Edited
18/06/2024

Condition category
Musculoskeletal Diseases

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

Plain English summary of protocol

Background and study aims
Osteoarthritis (OA) is a condition of musculoskeletal pain with approximately 450,000 individuals living with OA in Wales. Mild to moderate knee OA, not severe enough to warrant joint replacement, and resistant to nonsurgical options, represents a specific management challenge. Genicular artery embolization (GAE) is an interventional radiology procedure that aims to relieve pain by embolising the pathological new vessels while maintaining the larger vascular supply to the bone. It is done as a day case using local anaesthesia. A catheter is passed into the femoral artery and angiography is performed to identify the blood vessels supplying the area of increased vascularity. Once the abnormal new vessels are identified, a microcatheter is navigated into them under X-ray guidance. Tiny embolization particles are then delivered to the area of increased vascularity until the blood flow is stopped. GAE is the focused embolization of the pathological neovessels, with preservation of the genicular artery. This project will explore the effectiveness of this novel interventional radiological procedure as a treatment option to reduce pain and improve joint mobility, overall quality of life and well-being in patients living with mild-moderate knee OA. Additionally, the project aims to reduce pressure on primary care services, alongside physiotherapy and occupational therapy waiting lists. As the first known study in Wales to investigate the potential benefits of this procedure, it is hoped this study will realise the benefits of this intervention and ultimately lead to widespread adoption within Wales. The procedure is recommended by NICE, but not yet approved. This project, if successful, will act as a business case for the approval of the procedure.

Who can participate?
Patients aged >40 years old with moderate to severe knee pain from mild to moderate OA of the knee

What does the study involve?
The participants will be recruited from the orthopaedic clinics. Following a research clinic appointment, participants will undergo an MRI scan of the knee and will be booked for the procedure. The procedure itself is done as a day case. This project will explore the effectiveness of this novel interventional radiological procedure as a treatment option to reduce pain and

improve joint mobility, overall quality of life and well-being in patients living with mild-moderate knee OA. This will be assessed by sending electronic questionnaires to the participants at regular intervals for up to 2 years.

What are the possible benefits and risks of participating?
Possible benefits comprise an improvement in the symptoms (including pain) related to knee OA, a reduction in the need for regular pain medications or steroid injections and their associated side effects, improvement in mobility, and in quality of life. Taking part in this study will also help to provide important information about this procedure, with the hope it will be adopted and offered as a routine treatment for knee OA in Wales.

Possible risks are associated with the MRI scan which requires the patient to place their lower body in the scanner for about 20-30 minutes. Some patients may feel claustrophobic while in the MRI scanner. The MRI staff can always hear the patient if they are feeling uncomfortable, and they can request for the scan to be stopped at any time. The MRI also requires the administration of a dye, MRI contrast, which is used to enhance details, such as blood vessels on the scan. There is the risk of allergic reaction to the MRI contrast, however, established pathways exist within Radiology to manage any reactions. A very rare risk of receiving MRI dye is NSF (nephrogenic systemic fibrosis). This is only seen in patients with deranged kidney tests. You will receive blood tests prior to the MRI to ensure your kidney tests are satisfactory.

The GAE procedure carries the following risks (please note that most of these risks are rare and the Interventional Radiology team are adept at dealing with them) for pain, bleeding, and minor bruising. GAE also requires the use of a contrast dye to clearly look at the blood vessels. As with contrast agents used in MRI, there is a small risk of allergic reactions. There are also rare risks of blockage of an unintended blood vessel (referred to as non-target embolisation) and infection. There is a very rare risk of damage to the blood vessel causing a compromise to the blood supply of the leg. This damage is exceedingly rare with experienced operators.

Where is the study run from?
Royal Gwent Hospital, Wales (UK)

When is the study starting and how long is it expected to run for?
February 2022 to January 2026

Who is funding the study?
Bevan Commission on behalf of the Welsh Government (UK)

Who is the main contact?
Dr Nimit Goyal, nimit.goyal@wales.nhs.uk (UK)

Contact information

Type(s)
Principal investigator

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Additional identifiers

Clinical Trials Information System (CTIS)
Nil known

Integrated Research Application System (IRAS)
315730

ClinicalTrials.gov (NCT)
Nil known

Protocol serial number
IRAS 315730, CPMS 54898

Study information

Scientific Title
Genicular artery embolisation as a minimally invasive intervention to manage patients with mild-moderate osteoarthritis of the knee – setting up a new innovative service for Welsh patients.

Acronym
GO Wales

Study objectives
This project is the first of its kind within Wales, exploring the use of genicular artery embolisation (GAE) to treat and manage osteoarthritis (OA) of the knee, an often life-altering condition. GAE has been shown to provide longer-term pain relief compared to current non-surgical treatments. As technology and scientific evidence increase in the field of embolisation, we are looking to provide this potentially pain-reducing treatment for the people of the local population and beyond.

With increasing waiting times creating a backlog of patients waiting to be seen across almost all disciplines, a problem exacerbated by the events of the pandemic, alternative treatment options have never been so important. Through a system-wide approach, we are looking to increase the diversification of the workforce being used to tackle increasing wait times, and importantly look to positively impact the lives of these patients. Many of the patients with mild-moderate OA are of working age, therefore as well as improving the quality of life for these patients and their families, a national socioeconomic benefit may be realised by creating opportunities to return to work and stay at work.

A recent NICE overview (NICE, 2021) of the procedure has cited the procedure's efficacy in the following areas:
1. Pain relief
2. Improvement in knee symptoms and function
3. Reduction in medication and physical therapy

Ethics approval required
Old ethics approval format

Ethics approval(s)
Approved 17/11/2022; East Midlands- Leicester South Research Ethics Committee (Equinox House, City Link, Nottingham, NG2 4LA, UK; +44(0)207 104 8193; leicestersouth.rec@hra.nhs.uk), ref: 22/EM/0239

Study design
Single-centre prospective feasibility study

Primary study design
Interventional

Study type(s)

Treatment

Health condition(s) or problem(s) studied
Treatment of pain associated with osteoarthritis of the knee

Interventions
This project looks to explore the effectiveness of a novel interventional radiological procedure, genicular artery embolisation (GAE), as a treatment option to reduce pain, and improve joint mobility, overall quality of life and well-being in those patients living with mild-moderate osteoarthritis (OA) of the knee. As the first known study in Wales to investigate the potential benefits of this embolisation procedure, it is hoped this study will realise the benefits of this intervention and lead ultimately to widespread adoption within Wales.

As a prospective feasibility study, this project aims to recruit a limited number of patients who fit the relevant inclusion and exclusion criteria. Potential participants will be screened within the orthopaedic clinic and contacted by the clinical team in the first instance. They will also be provided with a Participant Information Sheet. This initial contact will be followed up with a phone call by the research team at least 48 hours after the initial contact where the team member will be able to answer some of the queries that the participant may have. Patients willing to participate in the study will be invited to attend the research clinic. In the clinic, participants will be seen by a medical member of the research team and the procedure will be explained in greater detail. They will get a chance to ask any questions that they may have and if willing to go ahead, consent will be obtained. The inclusion and exclusion criteria will be clarified. All patients require a knee X-ray within 6 months and if one has not been done in that time period, an X-ray will be organised during the same visit. If the X-ray confirms the grade of OA to be KL grades 1-3, participants will be given the option to participate in the trial. Following informed consent, recruited participants will have a pre-assessment check done during the same visit. All participants then undergo a contrast-enhanced MRI of the knee. Relevant baseline clinical information will be collected, including data relating to past and current conservative treatments and medication usage to support the line of inquiry posed by recent NICE recommendations to elucidate which patients would most benefit from this procedure.

A series of validated Patient Reported Outcome Measures (PROMs) will be utilised to collect information regarding perceived pain levels and quality of life. This will include the EuroQol 5 Dimension instrument (EQ-5D-5L), Oxford Knee Score (OKS) and Western Ontario and McMaster Osteoarthritis Index (WOMAC). Pain will also be assessed using the Visual Analogue Scale (VAS) validated tool. Participants will undergo the GAE procedure, conducted by a consultant interventional radiologist. The procedure itself will be performed in line with techniques described in the literature, supported by a multidisciplinary Radiology Team consisting of Radiology nurses and diagnostic radiographers. Patient-reported experience measures (PREMs) will also be collected, to gain an understanding of the experience, acceptability, and pain levels of the procedure itself.

Participants will be followed up at 1, 3, 6, 12 and 24 months, where the PROMS will be repeated. The collection of the study PROMS and PREMs will be carried out with the support of the ABUHB Value-Based Healthcare Team. Information will also be collected pertaining to any procedure-based complications, medication usage and visits to healthcare professionals (associated hospital admissions, primary care appointments, physiotherapy appointments, and orthopaedic clinic appointments).

Intervention Type

Procedure/Surgery

Primary outcome(s)
Safety measured using adverse events logs and clinical data throughout the study:
1. Adverse events
2. Procedural outcomes
3. Technical complications
4. Side effects of the procedure

Efficacy measured using PROMs including validated questionnaires to ascertain reduction in pain and improvement in quality of life at baseline and then at 1, 3, 6, 12 and 24 months following the procedure:
1. Pain measured using the Visual Analogue Scale (VAS) validated tool
2. Pain and Quality of life measured using the EuroQol 5 Dimension instrument (EQ-5D-5L)
3. Pain and Quality of life measured using the Oxford Knee Score (OKS)
4. Pain and Quality of life measured using the Western Ontario and McMaster Osteoarthritis Index (WOMAC)

Key secondary outcome(s))
1. Patient experience and tolerability measured using patient-reported experience measures (PREMs) at baseline and at 3 months
2. Effectiveness of genicular artery embolisation (GAE) from a technical perspective measured using clinical data throughout the study

Completion date
31/01/2026

Eligibility

Key inclusion criteria
1. Moderate to severe knee pain (VAS > 50 mm), and
2. Pain refractory to at least 3 months of conservative therapies (anti-inflammatory drugs, physical therapy, muscle strengthening, or intra-articular injections), and
3. Mild-moderate osteoarthritis of the knee as determined by Trauma and Orthopaedic procedure (previous Kellgren-Lawrence grade 1, 2 or 3 on a radiograph of the knee)
4. Ages > 40 years old

Participant type(s)
Patient

Healthy volunteers allowed
No

Age group
Mixed

Lower age limit
40 years

Sex

All

Total final enrolment
31

Key exclusion criteria
1. Current local infection
2. Life expectancy less than 6 months
3. Known advanced atherosclerosis, which is known lower extremity vascular or lower extremity symptoms thought to be secondary to arterial vascular disease (eg claudication, ischemic rest pain)
4. Rheumatoid or infectious arthritis
5. Prior knee surgery
6. Uncorrectable coagulopathy including INR > 2.5 or platelets < 30,000
7. Iodine allergy resulting in anaphylaxis
8. Renal dysfunction as defined by GFR (eGFR) of <45 obtained within the past 60 days
9. Contraindications for MR Imaging (such as claustrophobia, metallic fragment or foreign bones, implants or prosthesis)
10. IV contrast allergy characterized by anaphylaxis or anaphylactoid reactions.
11. Unable to provide written informed consent
12. Unable to understand written English Language (required to complete validated PROMs)

Date of first enrolment
25/11/2022

Date of final enrolment
31/01/2024

Locations

Countries of recruitment
United Kingdom

Wales

Study participating centre
Grange University Hospital
Aneurin Bevan University Health Board
Caerleon Rd
Llanfrechfa
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NP44 8YN

Sponsor information

Organisation
Aneurin Bevan University Health Board

ROR
https://ror.org/045gxp391

Funder(s)

Funder type
Research organisation

Funder Name
Bevan Commission on behalf of the Welsh Government

Results and Publications

Individual participant data (IPD) sharing plan
The datasets generated and analysed during the study will be available upon request from the Chief Investigator, Nimit Goyal, nimit.goyal@wales.nhs.uk

IPD sharing plan summary
Available on request

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
HRA research summary			28/06/2023	No	No
Participant information sheet	version 1.2	16/11/2022	24/01/2023	No	Yes