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Can osteoarthritis of the knee be treated by blocking abnormal blood vessels in the knee? (Study 2)

Submission date
08/03/2021

Recruitment status
No longer recruiting

Registration date
12/03/2021

Overall study status
Completed

Last Edited
20/09/2023

Condition category
Musculoskeletal Diseases

[X] 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 is a condition that causes joints to become painful and stiff. It's the most common type of arthritis in the UK. The main symptoms of osteoarthritis are joint pain and stiffness, and problems moving the joint.
The study aims investigate a new treatment for the pain caused by osteoarthritis (OA) of the knee called genicular artery embolisation (GAE) which involves surgically blocking a blood vessel in the knee. This research aims to investigate whether GAE is acceptable for patients and reduces patients' symptoms

Who can participate?
Patients aged 45 years or above with mild to moderate osteoarthritis of the knee joint that is not severe enough to warrant knee replacement surgery at this time.

What does the study involve?
Participants will be split into 2 groups. One will have the knee genicular artery embolisation procedure. The other will undergo a placebo procedure. In the embolisation procedure, small particles will be injected to block abnormal arteries in the knee. In the placebo procedure normal saline will be injected. A computer system will randomly select procedure groups. Participants will not told which group you were allocated to until 1 year post-operatively (except in case of emergency). Both groups will have knee MRI scans pre-operatively and 1 year post-operatively. Both groups will complete assessments and questionnaires pre-operatively, and post-operatively at 1 month, 3 months, 6 months & 1 year. In total there will be 6 visits to site (including 1 at the university).

What are the possible benefits and risks of participating?
The possible benefit is the reduction of pain in the treated knee. The risks are bruising, infection, allergic reaction, nerve damage, non-target embolisation, skin ischaemia and radiation exposure.

Where is the study run from?
Royal Berkshire Hospital (UK)

When is the study starting and how long is it expected to run for?
December 2020 to January 2024

Who is funding the study?
Varian Medical Systems UK Limited

Who is the main contact?
Dr Mark Little, Mark.little@royalberkshire.nhs.uk

Contact information

Type(s)
Scientific

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Additional identifiers

Clinical Trials Information System (CTIS)
Nil known

Integrated Research Application System (IRAS)

286849

ClinicalTrials.gov (NCT)
Nil known

Protocol serial number
CPMS 47507, IRAS 286849

Study information

Scientific Title
Genicular artEry embolisatioN in patiEnts with oSteoarthrItiS of the knee II (GENESIS II)

Acronym
GENESIS II

Study objectives
Embolization of the abnormal hypervascular process arising from branches of the genicular arteries reduces pain in patients with knee osteoarthritis (OA).

Ethics approval required
Old ethics approval format

Ethics approval(s)
Approved 15/12/2020, London-Hampstead REC (Ground Floor, Temple Quay House, 2 The Square, Bristol, BS1 6PN; +44 (0)207 104 8340; hampstead.rec@hra.nhs.uk), ref: 20/LO/1226

Study design
Single site double blind interventional randomized controlled trial

Primary study design
Interventional

Study type(s)
Treatment

Health condition(s) or problem(s) studied
Osteoarthritis of the knee

Interventions
Those participants adhering to the study inclusion criteria will be assessed by the interventional radiology research team. They will have knee embolisation discussed as an option for treatment, stressing the experimental nature of the intervention. It will also be asserted that patients that fail to gain a clinical benefit from knee embolisation can go on to have standard surgical/non-surgical treatments. Patients will be informed that the research involves a control (sham) arm in which they will not undergo the embolisation procedure, instead they will have 2ml of saline injected into their knee arteries-the remainder of the procedure is otherwise identical between the two groups. Patients will be blinded to the treatment arm until follow up is complete (1-year MRI and follow-up assessments). Randomisation will be perfomed at the time of intervention using a computational randomisation generator by a member of the team not directly involved

in the reaserch study (radiographer/scrub nurse). Randomisation will be 1:1. Whilst research participants will be blinded to the intervention, IRs will be aware of the treatment arm (non-blind). This is for safety reasons as it is important for Interventional Radiologists (IRs) to assess the quantity and suspension of embolic
material in the treatment arm.

Patients will undergo MRI safety screening prior to imaging as is standard clinical practice. Contrast-MRI imaging of the knee will be performed at baseline, and 1 year post procedure.

Prior to the embolisition procedure, patients will complete Knee Injury and Osteoarthritis Outcome Score (KOOS), Visual Analogue Scale (VAS) pain score, and medicines use questionnaires. These will be repeated at 1, 3, 6, and 12 months post procedure. Participants will also attend an assessment procedure at the Centre for Integrative Neuroscience and Neurodynamics at the University of Reading in the pre-intervention period, to undergo neural, psychological and behavioural assessment. This will take the form of an fMRI scan of the brain, to acquire images relating to anatomy, function and instrinsic connectivity. Patients will also complete questionnaires to formulate a psychological profile of criteria relevant to the prediction of poor clinical outcomes and pain processing. Lastly, a sensory pain assessment including such measurements as conditioned pain modulation (CPM) and temporal summation (TS) will be completed to quantify a pain profile. This pre-surgical assessment in it's entirety will last 1-2 hours and was also used in GENESIS.

Following the embolisation procedure, patients will complete a satisfaction questionnaire to assess the acceptability of the intervention. This will be completed after the procedure, up to the first follow up.

Feasibility study (GENESIS) registered at ISRCTN (https://www.isrctn.com/ISRCTN18266598).

Intervention Type
Procedure/Surgery

Primary outcome(s)
Pain assessed at baseline and one year using:
1. The Knee Injury and Osteoarthritis Outcome Score (KOOS)
2. Visual Analogue Scales (VAS)
3. Analgesia diary

Key secondary outcome(s))
1. Safety at 1 year MRI and any adverse event timepoint assessed by collecting all complications attributable to the GAE procedure prospectively as recorded in the patient's electronic medical notes and study file
2. Neural indicators assessed at baseline psychometric assessment & baseline MRI neuroimaging
3. Patient acceptability of GAE procedure is measured using a patient satisfaction questionnaire at 1 month
4. Health economic cost effectiveness is measured at the trial end using standard NHS costing

Completion date
01/01/2024

Eligibility

Key inclusion criteria
1. Participant is willing and able to give informed consent for participation in the study
2. Participants aged 45 years or above
3. Grade 3 knee OA on X-ray as per Kellgren-Lawrence (KL) Grading Scale
4. Knee pain for at least 3 months resistant to conservative treatment
5. 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)

Participant type(s)
Patient

Healthy volunteers allowed
No

Age group
Adult

Sex
All

Key exclusion criteria
1. Rheumatoid arthritis or infectious arthritis
2. Severe knee OA (grade 4 on x-ray as per Kellgren-Lawrence Grade)
3. Renal impairment: eGFR <45. Assessed from medical records or a blood test if required as is part of standard clinical practice when considering a patient for a therapeutic intervention
4. Patients with a bleeding diathesis, or other bleeding risk such as patients on warfarin which cannot be stopped easily (e.g. patients with metallic heart valves). assessed by asking the patient and from medical records
5. Requires oxygen on ambulation. assessed by asking the patient and from medical records
6. Low life expectancy (<1 year)
7. Communication difficulty due to language barriers
8. Contraindication to MRI
9. Any other significant disease or disorder which, in the opinion of the recruiting physician, may put either the participants at risk because of participation in the study, or may influence the result of the study, or the participant's ability to participate

Date of first enrolment
01/05/2021

Date of final enrolment
01/06/2022

Locations

Countries of recruitment
United Kingdom

England

Study participating centre
Royal Berkshire Hospital
Royal Berkshire NHS Foundation Trust
London Road
Reading
United Kingdom
RG1 5AN

Study participating centre
University of Reading
Department of Psychology
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RG6 6BZ

Sponsor information

Organisation
University of Reading

ROR
https://ror.org/05v62cm79

Funder(s)

Funder type
Industry

Funder Name
Varian Medical Systems UK Limited

Results and Publications

Individual participant data (IPD) sharing plan
The current data sharing plans for this study are unknown and will be available at a later date

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?
HRA research summary			20/09/2023	No	No
Participant information sheet	Participant information sheet	11/11/2025	11/11/2025	No	Yes