Insert local contact details and Site Logo

Study title: *Genicular Embolisation for Knee Osteoarthritis trial (GEKO)*

Patient Information Sheet
V2.0 20 June 2025

We would like to invite you to take part in the GEKO research study, to help us find out if there is a way to reduce knee osteoarthritis pain.

Before you decide if you want to take part, it is important for you to know why this research is being done and what it would involve.

Please take time to read this information and discuss it with others if you wish.

If you have any questions or would like more information, please ask us. Our contact details are at the end of this document or please email geko@ndorms.ox.ac.uk

Summary

- The GEKO 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.
- If you are eligible and decide to join the study, you will be randomly assigned to either receive the active treatment (GAE) or a placebo procedure. You won't be able to choose which procedure you will receive.
- The active treatment (GAE) involves a procedure where tiny beads are used to block small blood vessels around the knee. The placebo procedure is where a similar procedure is done, but instead of the beads, a simple saline solution (salt water) is injected.
- The placebo procedure is solely for research purposes. It helps us make sure that any changes in knee pain are due to the active treatment (GAE) and not because of the placebo or other reasons.
- The procedure will be done using local anaesthesia (numbing the area), and you should only need to stay at the hospital for the day if everything goes as planned.
- You'll be asked to fill out questionnaires about your health and recovery before the procedure, and then again at 6 weeks, 3, 6, and 12 months after the procedure. This helps us to understand your experience better.
- We will also ask you to come back for follow-up appointments at the hospital, where we may do 1 or 2 MRI scans over the next 6 months to understand how the treatment may affect your pain.
- Patients like you have shared how important finding a good solution to knee pain is and their input has helped us design this study and the information you're reading now.

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Study Background

Osteoarthritis is the most common type of arthritis, with the knee joint being the most often affected.

The most common symptom of knee osteoarthritis is pain.

Many people are treated with physiotherapy and painkillers, but these may not control the pain well. In cases where there is substantial joint damage, often referred to as 'late-stage arthritis', knee replacement surgery may be an option.

At present, there are limited treatment options for patients between having physiotherapy and pain killers, and more complex knee replacement.

The GEKO study is looking at a possible new treatment option for patients with moderate to severe knee pain called **genicular artery embolisation**. If it works, it could help a lot of people with knee osteoarthritis pain.

What is genicular artery embolisation?

In knee osteoarthritis, extra blood vessels can grow from the normal blood vessel that supplies blood to the knee (the genicular artery) (Fig 1.). This contributes to inflammation and pain in the knee joint.

The genicular artery embolisation procedure is designed to reduce pain by blocking (embolising) the extra blood vessels, while still preserving the larger blood flow to the bone (Fig 2.).

During the procedure, a tube is inserted into an artery in the groin and passed into the genicular artery. Tiny particles (microbeads) are then injected into the extra blood vessels.

The microbeads are smaller than grains of sand and contain gelatine and water. After being injected into the body for embolisation, they dissolve after a few days.

The microbeads used for this procedure contain gelatine from pig products. Please **do not** take part in the study if you have personal or religious objections to the use of gelatine from pigs in your treatment. Unfortunately, we cannot offer an alternative in this study.

This treatment is not thought to have an impact on the progression of osteoarthritis, only possibly reducing the pain associated with it.

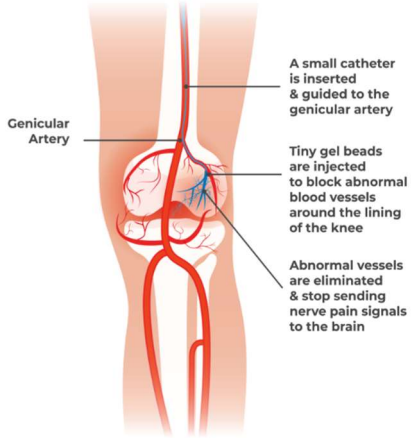

Figure 1.

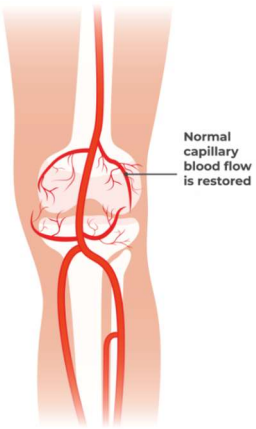

Figure 2.

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What is the purpose of the study?

We currently do not know whether genicular artery embolisation can improve knee pain. In the GEKO study, we are assessing whether blocking off these extra blood vessels using microbeads will reduce knee pain from osteoarthritis.

Embolisation is a well-established procedure used in the NHS, which involves the insertion of a solution of microbeads, salt and sterile water into blood vessels to block them. The embolisation procedure is already used to treat some liver, prostate, and womb conditions.

There have been some research studies using embolisation in the treatment of knee pain. However, there are no large-scale studies to help us know whether this new treatment can improve knee pain.

A randomised controlled trial is needed to answer this question. This involves assigning participants, at random, to the different treatments.

Dividing people into groups in this way is the standard and most reliable way to see how good a treatment is. This process is the only way to ensure the groups are as similar as possible before any treatment starts and then allows a fair comparison between how people in each treatment group do. This is to ensure any differences in knee pain are due to the treatment and no other factors.

In the GEKO study, the genicular artery embolisation treatment will be compared to a placebo procedure – a similar procedure, but instead of blocking off the extra blood vessels using microbeads, only saline water (a mixture of salt and sterile water) will be injected into your knee. Injecting saline water into your body is harmless.

The placebo procedure is solely for research purposes. It is essential to make sure any changes in knee pain are due to the active treatment (embolisation) and not due to the placebo or other reasons.

If you join the study, you will have an equal chance (50:50) of receiving either the treatment involving the blocking of the extra blood vessels (embolisation) or placebo.

Neither you or the team performing the procedure for you will be able to choose whether you have the treatment or placebo.

We will recruit 216 patients (participants) throughout the UK from NHS hospitals and using information from questionnaires and images taken of the knee over the period of a year, we will compare and assess whether the new treatment compared with a placebo procedure changes knee osteoarthritis pain.

We hope our study will provide evidence to better inform treatment options available for patients in the NHS.

Why have I been invited?

You've been invited to take part in the GEKO study because:

- You have knee osteoarthritis (OA) and ongoing knee pain.
- You have already tried non-surgical treatments for knee OA, as recommended by your doctor.
- Based on your medical history, your doctor or the study team believes you may be eligible to participate

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Do I have to take part?

No, taking part in the study is completely voluntary. You do not have to take part just because we have spoken to you or given you this Information Sheet and it will not affect any medical care you currently have or hope to have in the future.

What will happen to me if I decide to take part?

The diagram below summarises what would be involved if you take part in the study. Further detail is provided below.

1. Clinic

In clinic, a member of the clinical research team will have gone through the study and procedure in detail with you, provided you with this information sheet, and answered any questions that you have.

2. Consent

After you have had time to read this Patient Information Sheet and if you are interested in taking part in this study, we will ask you to complete and sign a Consent Form. You will be given the option to complete this either on paper or electronically. This is to confirm you are happy to join the study and understand what it involves.

3. Procedure and Randomisation

You will be invited at a later date to come to the radiology (X-ray) department for the procedure on your knee. This would likely be 6-8 weeks after you have signed the consent form, depending on your local hospital site waiting times. Your local doctor / care team will provide you with information on the appointment. General information on Genicular Artery Embolisation can be found here: Genicular Artery Embolisation | BSIR

Before you undergo the procedure, we will ask you to fill in a questionnaire which should take you roughly 10 minutes to complete. You will be given the option to complete this either on paper or electronically. The questionnaire helps us to find out how you feel, how you are managing your knee pain, and how your knee pain is affecting your daily life. Since the procedure is for people with ongoing knee pain, if your pain is no longer moderate to severe knee pain you may no longer be eligible to continue with the study. In that case, we'll make sure you are referred back to NHS care.

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The procedure is performed by a specialist doctor expert in these types of procedures (an Interventional Radiologist). They will start by injecting some local anaesthetic into your groin and then inserting a small plastic tube into the groin artery.

Using X-Rays or ultrasound to guide them, the radiologist will then guide a second smaller plastic tube (called a catheter tube) from the groin to the arteries around the knee. They will inject some X-Ray dye (iodine-based contrast dye) into the knee arteries through the catheter to check that the extra blood vessels are present. This is called an angiogram. This process will take around 20-30 minutes. Injecting dye into your body is considered harmless.

If the extra blood vessels are **not** present, you will **not** be eligible to continue in the study, and you will be referred back to NHS care. You will need bed rest in hospital for a minimum of 2 hours, and in accordance with local hospital policy, before going home on the same day. You should not need any further treatments. If so, you will be contacted by the clinical team 6 weeks later to check if you had any issues following the checking of your knee. This may be by telephone or in person during a clinic visit depending on your local hospital. If you have any pain or concerns during these 6 weeks, please contact your local hospital earlier.

If you **do** have extra blood vessels present in your knee, you will then be randomised to receive either the placebo procedure or the procedure with embolisation (blocking of the blood vessels with tiny beads), immediately following the first angiogram on the same day.

If you are randomised to the procedure with embolisation (**Group 1**), the next step would be that a tube would be inserted into an artery in the groin and passed into the genicular arteries to the area of the new extra vessels. Tiny beads made from gelatine are then injected into the extra blood vessels. This blocks them (embolisation) and restores normal blood flow around the knee joint. Only a tiny amount of liquid (0.5-2 ml) containing the microbeads.

For those randomised to the placebo (**Group 2**) this involves a similar procedure to ensure a fair comparison. The only difference is that the **microbeads will not be injected into the extra blood vessels**, and only saline water will instead.

For both groups, an image (angiogram) will be taken of your treated knee before and after the procedure.

At the end of the procedure, the radiologist will remove the plastic tube (catheter), and a skin dressing will be applied.

Both procedures will be performed with you awake and under local anaesthetic. You will be unable to see the procedure that is being undertaken, and headphones will be used to ensure you do not hear anything that may make them aware of which group they are in.

For all participants, the whole hospital visit, including procedure, will take a day and will be performed during normal working hours.

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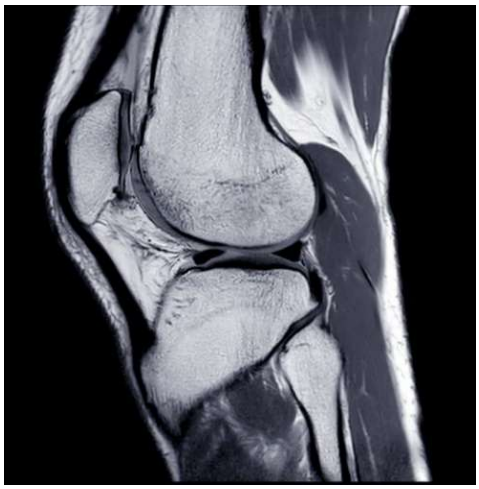
What happens after my procedure?



Following the procedure, you will usually go home on the same day. You will receive advice on managing your skin dressing. There will be no specific extra activities for you to do. You can walk and undertake your usual activities. In very rare cases a complication may arise that needs you to stay in hospital overnight for monitoring or treatment. Please see the section on *What are the possible disadvantages or risks to taking part?* for more information on possible complications.

You can continue doing gentle exercise, but we would recommend you avoid strenuous exercise or lifting heavy objects.

4. Follow up:

Questionnaires

The research team in Oxford will send you a questionnaire at 6 weeks, 3 months, 6 months, and 12 months following your procedure. Each will take around 10 minutes to fill out and will ask about your pain, health and recovery since your treatment. You can choose to complete these online or by post. We may get in contact by post, email or phone to remind you to complete the questionnaires.

The research team in your hospital will also have access to your answers.

MRI scans after the procedure

Everyone participating in the study will have a standard MRI scan at 6 months after the procedure to help understand why any changes in your knee pain have occurred.

In addition to this, the first 90 people who agree, will be asked to have a special contrast MRI scan at 3 months after the procedure.

The difference between a standard MRI scan and a contrast MRI is that it uses a gadolinium contrast dye, which when injected into the body helps improve the clarity and quality of the MRI scan images of your body structures. It improves the visibility of inflammation, blood vessels, and blood supply in the knee, which will be assessed by specialist researchers.

Gadolinium dye is considered to be harmless. Rarely (less than 1% of people), there may be an allergic reaction to the dye.

Participants will be invited via email or letter by their local hospital to have the 6-month MRI scan and a more specific contrast MRI scan at 3 months (if having this scan) following the study procedure.

A researcher will *contact you / meet you* [*delete accordingly*] to go over the information sheet, explain what you would need to do, and go through a screening form with you to check if it is safe for you to participate. If you are suitable and agree, we would ask you to come to the *[please add name of imaging centre here]* for the study scan**.** Before you come to your visit, please let us know if you wear contact lenses or glasses.

On arrival, one of our research team would meet you to review what participation will involve and answer any questions you may have. If you are happy to continue, they may then ask you to sign a local hospital consent form, in accordance with their local policies. [*delete if not needed*] Someone will check that it is still safe for you to have an MRI scan.

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You would be asked to lie still on a table inside the MRI scanner while having a series of MRI scans over a period of about 45 minutes. The entire research visit will last for about 90 minutes. If someone comes with you, the research team can show them to an area where they can wait.

These scans will help us better understand the effect of the treatment or placebo on the abnormal blood vessels in the knee and how this may affect your pain.

Routine Hospital Data

Local research teams will review your hospital medical records about any visits to healthcare professionals related to your knee up to 12 months after your procedure. This is so we can find out about any further treatment you have needed for your knee or any complications you may have suffered.

We would also like to retain your identifiable information (i.e., name and NHS/Community Health Index (CHI) number) for up to five years following the end of the study to enable long-term follow-up using routinely collected NHS data. This will allow us to see if the treatment has helped in the long term. Collection of this data will be subject to further funding being secured. If you give your permission, then only authorised individuals from the research team will access this information after you have entered the study.

Agreeing to long-term follow up (after 1 year) is not essential to be able to take part in GEKO. You can choose for your data not to be used in this way.

However, it could significantly improve our understanding of how effective this treatment is in the longer term.

Will I know what treatment I have?

No. GEKO is a “blinded” study, so you will not know which treatment you have had during the course of the study. The NHS health professional that performs your follow-up MRI scans will also not know which treatment group you are in. This will help us to compare the two treatments as fairly as possible.

If you would like to know if you had the embolisation procedure or the placebo procedure, the central GEKO team can tell you at the end of the study.

FURTHER TRIAL INFORMATION

What are the possible benefits of taking part?

Your knee pain may or may not improve. We cannot guarantee a benefit to participants who take part in this study. We hope that by carrying out the study we will gather evidence to show whether there is a way to reduce knee osteoarthritis pain. The results we get from the study are likely to benefit future patients like yourself with knee pain and osteoarthritis.

What are the possible disadvantages or risks to taking part?

Taking part in the study will not change the standard of care you receive.

With all medical procedures, there is always a very slight chance of risk of problems. All risks to you will be assessed by your treating clinician and discussed with you. Potential complications associated with an embolisation procedure include bleeding, bruising, local pain, infection, and mild allergic reactions. Rare but serious complications that may occur include injury to local nerves or blood vessels, unintended embolisation of a blood clot or the embolisation material, serious allergic reactions, worsening or lasting pain.

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If you have any questions or concerns about the complications associated with the treatments, please speak to your local care team.

If you take part in this study, you will have an X-ray guided interventional procedure on your knee (angiogram) and you will have knee images (radiographs) taken. Some of these will be extra to those that you would have if you did not take part. These procedures use ionising radiation to form images of your body and provide us with other clinical information. Ionising radiation can cause cell damage that may, after many years or decades, turn cancerous.

We are all at risk of developing cancer during our lifetime. The normal risk is that this will happen to about 50% of people at some point in their life. Taking part in this study will add only a very small chance (0.0005%) of this happening to you, which was the conclusion of the Radiation in Clinical Research team at Oxford University Hospitals NHS Foundation Trust after assessing the radiation risks within this study.

MRI is safe and does not involve any ionising radiation (x-rays). However, because it uses a large magnet to work, MRI scans are not suitable for everybody. You would be asked to answer some safety questions to determine if you can take part. Normally, we would need more information before you take part in the research MRI scan if you have a heart pacemaker or stent, mechanical heart valve, mechanical implants such as an aneurysm clip, joint replacement (e.g. hip/knee), or if you carry other pieces of metal that have accidentally entered your body.

While there is no evidence that MRI is harmful to unborn babies, as a precaution, the Department of Health advises against scanning pregnant women unless there is a clinical benefit. We do not test for pregnancy as routine so if you think you may be pregnant you should not take part in this study.

While very rare, tattoos can occasionally warm up in the scanner. Please inform the person operating the scanner immediately if you feel any heating. If you have a new tattoo, you should not take part in a scan until 48 hours after receiving the tattoo.

If you think you might be claustrophobic, please talk to the researcher in advance, or let the person operating the scanner know before you start.

Some of the scans are noisy, so we will give you earplugs to make this quieter for you. It is important that these are fitted correctly, as they are designed to protect your hearing.

In preparation for your scan and for your comfort and safety we may ask you to change into scrubs ("pyjama-style" top and trousers), available in a range of sizes. You may keep your underwear and socks on, but you will need to remove underwire bras. If you have a suitable non-wired bra, you may wear this instead. Do not wear any fabrics that contain metallic threads or are silver impregnated (often marketed as anti-microbial/bacterial or anti-odour/stink). Metal jewellery, including body piercing, must also be removed. If you wish to wear eye makeup to your scan, we will give you makeup removal wipes because you should not wear eye shadow or mascara in the scanner. If you wish, bring your own makeup to reapply. Lockers are provided to secure your personal belongings and clothing.

You will be introduced to the scanner carefully and allowed to leave at any stage. Whilst in the scanner you will have a call button, which you can press if you need to stop the scan or speak with the person operating the scanner.

Will my General Practitioner (GP) be informed of my participation?

If you agree to take part, and are randomised in the study, your GP surgery will be notified by letter and provided with a link to further study information. Your GP will not know which group you were allocated to.

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Will I be reimbursed for taking part?

There is no payment to people for taking part in the study, but reasonable travel expenses to study-specific appointments such as the MRI scans following your procedure can be reimbursed. Please ask the local research team for further details about this and keep any receipts.

Will my taking part in the study be kept confidential?

Yes. All study records and medical images will be identified only by a code. We will only use your contact information and informed consent form for the purposes of the study, if you would like to receive a summary of the results of this study or to contact you about future research. We will only use your names, date of birth, and NHS/CHI number where this is necessary for the purpose of long-term follow-up with routine NHS data (e.g. HES linkage).

Confidentiality will be maintained as far as it is possible, unless you tell us something which implies that you or someone you mention might be in significant danger of harm. In this case, we would have to inform the relevant agencies, but we would discuss it with you first.

We need to use information from you, your medical records, and your medical images for this research project.

The GEKO study will comply with the General Data Protection Regulation (GDPR) and Data Protection Act 2018, which will require data to be de-identified as soon as it is practical to do so. Personal data on all documents will be regarded as confidential. The processing of the personal data will be minimised by using a unique Participant Identification number on all study documents and any electronic databases.

We will only use your name, contact address, contact phone numbers (landline and mobile), email address, where this is necessary to contact you (all may not apply) for the purposes of the study:

- Send you the follow-up questionnaires and any reminder messages.
- Send you reminders via email to remind you to complete questionnaires.
- Send you a copy of your signed and dated Consent Form and a copy of this Participant Information Sheet.
- Send you a summary of the results of this study.
- Contact you about future research, but only if you have agreed to this.

Responsible members of the University of Oxford, and regulatory authorities and the relevant NHS Trust(s)/Health Board(s) may be given access to data for monitoring and/or audit of the study to ensure that the research is complying with applicable regulations.

All documents will be stored securely and only accessible by study staff and authorised personnel. The study staff will safeguard the privacy of participant's personal data.

What will happen to my data?

Data protection legislation requires that we, the University of Oxford (whose legal name is The Chancellor Masters and Scholars of the University of Oxford), state the legal basis for processing information about you. In the case of research, this is 'a task in the public interest.' The University of Oxford is the sponsor for this study and is responsible for looking after your information and using it properly.

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We will need to use information from you, your medical images and your hospital records for this research project. We will share your information related to this research project with the following types of organisations: Universities of Oxford and Nottingham, regulatory authorities, and from the NHS Trusts/Health Boards from where you are taking part.

This information will include your name, NHS number, sex, date of birth, and contact details. People will use this information to do the research or to check your records to make sure that the research is being done properly.

People who do not need to know who you are will not be able to see your name or contact details. Your data will have a code number instead.

International Transfers
Your personal data will not be shared outside the UK.

Once we have finished the study, we will keep some of the data so we can check the results. We will write our reports in a way that no-one can work out that you took part in the study.
We will keep your study data for the minimum period of time required by the University Policy on Management of Data, we will keep the research data for 5 years after the end of study.

What are your choices about how your information is used?

You can stop being part of the study at any time, without giving a reason, but we will keep information about you that we already have. You have the right to ask us to remove, change or delete data we hold about you for the purposes of the study. We might not always be able to do this if it means we cannot use your data to do the research. If so, we will tell you why we cannot do this.

If you choose to stop taking part in the study, we would like to continue collecting information about your health from central NHS records if funding is obtained for long-term follow-up and your hospital. If you do not want this to happen, tell us and we will stop.

You can find out more about how we use your information by:

- asking one of the research team by sending an email to geko@ndorms.ox.ac.uk
- calling us on 07584 887142
- contacting the University's Data Protection Officer data.protection@admin.ox.ac.uk
- looking at the University's privacy notice available at: https://compliance.admin.ox.ac.uk/research-data

If you would like to find out more about the use of confidential data in research, the HRA has developed a general information leaflet which is available at: https://www.hra.nhs.uk/planning-and-improving-research/policies-standards-legislation/data-protection-and-information-governance/gdpr-guidance/templates/template-wording-for-generic-information-document/

We may use third party service providers or subcontractors to help with some of the research activities we carry out (e.g., email service providers/companies to send study-related emails to you etc.). We may therefore share your personal data with these providers when it is necessary to do so to allow them to carry out the services we require them to provide. However, we require all our third-party providers to have appropriate security measures in place to protect your data, and we only allow them to process your data for the specific purposes we have stated in our instructions.

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Safety-related data will also be shared with the manufacturer of the embolisation beads to allow them to fulfil their legal responsibilities for monitoring the safety of the beads.

We will store any research documents with personal information, such as consent forms, securely at your local hospital and at the University of Oxford for 5 years after the end of the study, as part of the research record.

Authorised MRI scanning centre personnel at your Hospital Trust and the central research team at both Oxford and Nottingham University will have access to the MRI imaging data. MRI imaging data is assigned a unique ID as it is collected and stored in a secure database on University-managed IT systems. Due to the nature of the MRI images, they remain potentially identifiable, even after we destroy your personal details. Imaging data will be stored on archive tapes at the MRI location at your hospital and kept indefinitely, for quality control, and to facilitate further use of the scans where permission has been given.

For the GEKO study, your X-rays (angiograms) and MRI scan images will be securely transferred from your hospital to the University of Oxford and will also be accessed by the central research team at the University of Nottingham. These will include:

- A baseline MRI scan completed by your NHS health professional in the past year.
- X-rays (angiograms) taken during the procedure.
- For a small group of participants, a more specific contrast MRI scan will be done at 3 months after the procedure.
- All participants will have an MRI scan done 6 months after the procedure.

The scans may contain some personal information on them (date of birth and sex). All images and documents will be stored securely on Oxford University and Nottingham University managed IT systems and only accessible by study staff and authorised personnel.

If you agree to your details being held to be contacted regarding future research, we will retain a copy of your consent form securely at the central Clinical Trials Unit at Oxford until at 5 years after the end of the study when they will be removed from our database. We will keep the consent form, and your details separate from one another and any research data.

If you claim travel expenses for your additional clinic visits due to taking part in GEKO, you will be asked to complete an expense claim form, and your bank details will be stored for 7 years in accordance with the University of Oxford Financial Policy.

If you decide to take part in this study your local NHS Trust (Hospital) will use your identifiable data e.g. name, NHS number, home address and contact details to contact you about the research study, and to oversee the quality of the study. A copy of your fully signed consent form from this study will be given to you and a further copy kept in your medical records for as long as those records are retained.

If you agree to us keeping your NHS/CHI number to enable long term follow-up, using routinely collected NHS data, we will keep this information for 5 years from the end of the study.

Data protection regulation provides you with control over your personal data and how it is used. When you agree to your information being used in research, however, some of those rights may be limited in order for the research to be reliable and accurate. Further information about your rights with respect to your personal data is available at https://compliance.web.ox.ac.uk/individual-rights

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What if we find something unexpected?

It is important to note that the scans carried out as part of this study are for research purposes only. Therefore, these scans are no substitute for contacting your doctor if you have a medical problem.

Our scans are not routinely looked at by a doctor. Occasionally a possible abnormality may be detected. In this case, we would have the scan checked by a doctor. If the doctor felt that the abnormality was medically important, you would be contacted directly and further assessment arranged as necessary. You would not be informed unless the doctor considers the finding has clear implications for your current or future health. All information about you is kept strictly confidential. We may also contact your General Practitioner (GP) if study-specific results indicate you might need medical support.

All information about you will be kept strictly confidential.

What will happen if I don't want to carry on with the study?

Taking part in the GEKO Study is voluntary. You can stop being part of the study at any time, without giving a reason, but we will keep information about you that we already have. You have the right to ask us to remove, change or delete data we hold about you for the purposes of the study. We might not always be able to do this if it means we cannot use your data to do the research. If so, we will tell you why we cannot do this.

If you choose to stop taking part in the study, we would like to continue collecting information about your health from your hospital and central NHS records. If you do not want this to happen, tell us and we will stop.

What happens to the results of this study?

With your agreement, we will send you a summary of the study results at the end of the study. When you join the study, we will ask if you would like to have a copy of the results. The results will also be shared with patients, the general public, healthcare providers, clinicians, healthcare policy makers, commissioners, and national bodies (via charities and policy-making such as national guidelines) to improve future patient care. The results may also be published in an anonymised form, and presented in research reports, at scientific conferences, and in scientific journals. Any data that could identify you will not be included in the results.

A summary of the study results will be made available on the study website https://geko.octru.ox.ac.uk once the results have been published.

After the end of the study an anonymised study dataset (this is a form of information that we use from the study but has no identification of any participants) will be created and stored for as long as it is useful and may be shared with other researchers upon request or may also be used for teaching purposes.

We will work with our Patient and Public Involvement (PPI) group and other organisations to ensure the study results are seen by the public. We may also use social media (e.g. X (formerly Twitter) Bluesky/blogs).

What if I have a concern or a complaint?

If you have a concern about any aspect of this study, please speak with the GEKO research team: geko@ndorms.ox.ac.uk. They will do their best to answer your questions.

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We recognise the important contribution that volunteers make to medical research and will make every effort to ensure your safety and wellbeing. The University of Oxford, as the research sponsor, has appropriate insurance in place in the unlikely event that you suffer any harm as a direct consequence of your taking part in this study. If something does go wrong, you are harmed during the research, and this is due to someone's negligence, then you may have grounds for a legal action for compensation. While the Sponsor will cooperate with any claim, you may wish to seek independent legal advice to ensure that you are properly represented in pursuing any complaint. The study doctor can advise you of further clinical action and refer you to a doctor within the NHS for treatment, if necessary.

In terms of clinical treatment, the NHS provides this protection (NHS indemnity) to ensure that both patients and healthcare professionals are supported.

If you wish to complain about any aspect of the way in which you have been approached or treated, or how your information is handled during the course of this study, please contact the study research team by email: geko@ndorms.ox.ac.uk

or the study Chief Investigator: Prof. Andrew Price: andrewprice@ndorms.ox.ac.uk

You may also contact University of Oxford Research Governance, Ethics & Assurance (RGEA) or the director of RGEA at rgea.complaints@admin.ox.ac.uk

The Patient Advisory Liaison Service (PALS) is a confidential NHS service for England and Wales that can provide you with support for any complaints or queries you may have regarding the care you receive as an NHS patient. PALS is unable to provide information about this research study.

If you wish to contact the PALS team, please contact <insert relevant NHS site phone number and email> or visit the PALS website: https://www.nhs.uk/nhs-services/hospitals/what-is-pals-patient-advice-and-liaison-service/
For support in Scotland, please contact the Patient Advice & Support Service (PASS)
PASS national helpline phone number: 0800 917 2127
PASS website (webchat): www.patientadvicescotland.org.uk

How have patients and the public been involved in this study?

Members of the public that have undergone knee pain and treatment have helped develop this research study, this patient information document, and what research questions should be asked. The patients and public members will continue to be involved in the study, and we have a patient advisor as part of our study team.

Further information on public involvement of clinical trials can be found through the following links: https://www.nihr.ac.uk/get-involved/take-part-in-a-study

Who is organising and funding this research?

The GEKO study is supported, also known as sponsored, by the University of Oxford. The Surgical Intervention Trials Unit at Oxford will manage the study with Oxford Clinical Trials and Research Unit. The National Institute of Health Research (NIHR), Efficacy and Mechanism Evaluation (EME) programme, has funded the study. The embolisation beads used in the study will be supplied to the hospitals from the manufacturer free of charge.

Who has reviewed this study?

All research in the NHS is looked at by an independent group of people, called a Research Ethics Committee, to protect participants' interests. This study has been reviewed and given favourable opinion by HSC Research Ethics Committee A (REC) (REC Reference: 25/NI/0081).

Participation in future research

If you agree to us keeping your personal details for contacting you about future research, we will keep this information after the end of the study. We will retain a copy of your consent form securely at Oxford until such time as your details are removed from our database. We will keep the consent form, and your details separate from one another and any research data.

Further information and contact details

The GEKO research study team can be contacted:
by email: geko@ndorms.ox.ac.uk

by post: **GEKO**
Surgical Intervention Trials Unit (SITU)
Nuffield Department of Orthopaedics, Rheumatology & Musculoskeletal Sciences (NDORMS)
University of Oxford
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Windmill Road
Oxford
OX3 7LD

LOCAL CONTACT DETAILS

Thank you for considering taking part in the GEKO Study.

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