Comisiwn Bevan Commission

GIG CYMRU NHS WALES | Bwrdd Iechyd Prifysgol Aneurin Bevan University Health Board

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

GAE for OA in Wales

IRAS ID: 315730

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Participant Information Sheet

Introduction

This leaflet introduces a procedure, Genicular Artery Embolisation (GAE), as a treatment which aims to reduce the pain and symptoms of osteoarthritis (OA) of the knee. As someone who suffers with OA of the knee, your specialist doctor believes you are a candidate for GAE. We would therefore like to invite you to take part in this research study, looking at the introduction of GAE in Wales. Please take the time to read this information sheet and ask any questions which come to mind.

Who is organising the study?

The study is being done by the Interventional Radiology department in Aneurin Bevan University Health Board in association with the department of Trauma and Orthopaedics. The study is funded by the Bevan Commission Planned Care Innovation Program grant and sponsored by the Aneurin Bevan University Health Board.

Background of study

Musculoskeletal (MSK) conditions are a group of conditions which broadly affect the bones, joints, muscles, and spine. Common traits for the spectrum of MSK conditions are the presence of pain, discomfort, immobility, loss of dexterity and a negative impact on quality of life and wellbeing.

Osteoarthritis (OA) is considered a condition of MSK pain, and whilst precise prevalence data is lacking, it is thought that approximately 450,000 individuals are living with OA in Wales (Versus Arthritis OA Calculator). For those individuals with mild-moderate OA, or where joint replacement surgery has failed to deliver the desired outcomes, chronic pain can result in disability and limit quality of life.

One of the factors which is believed to be responsible for the pain associated with OA of the knee is growth of new blood vessels. These new vessels can develop throughout the knee joint bringing about increased oxygen supply and the growth of new sensory nerves which contribute towards the pain sensations of OA sufferers.

Geniculate artery embolisation (GAE) is an Interventional Radiology procedure that aims to relieve pain related to OA by blocking these new blood vessels (using tiny particles known as embolisation beads) while maintaining the larger blood supply to the bone.

What would taking part involve?

You have been informed of this research project by a member of the orthopaedics team and as you have expressed an interest, you have received this information sheet. You will receive a call a couple of days after receiving the leaflet which will aim to answer some of the queries you may have about the research. Please note that you do not need to make a decision regarding participation at this time. If, following the discussions over the phone, you are interested in knowing more about the project or taking part, you will be invited to a radiology clinic.

In the clinic, a member of the research team will go through the procedure in detail and answer any queries that you have. If you are happy to proceed, they will ask you to sign a consent form. You do not need to agree to participate in the clinic itself. You can always contact the Chief Investigator directly on the contact details at the end of this leaflet with a decision later. To assess your suitability for the GAE procedure, a knee X-ray will be performed (if it hasn't been done in the past 6 months) and you will have up-to-date blood tests done (if not done within last 60 days). Please note that suitability for inclusion in the study is determined by the knee X-ray and blood tests and there is small chance that you may not be eligible following these investigations. A member of the research team will discuss this with you, if relevant. In the clinic, you will also be asked to fill in an electronic survey called PROMs (Patient reported outcome measures). This survey will form the baseline against which any improvement will be compared on future surveys after the procedure. These future surveys will happen at 1, 3, 6, 12 and 24 months after the GAE procedure.

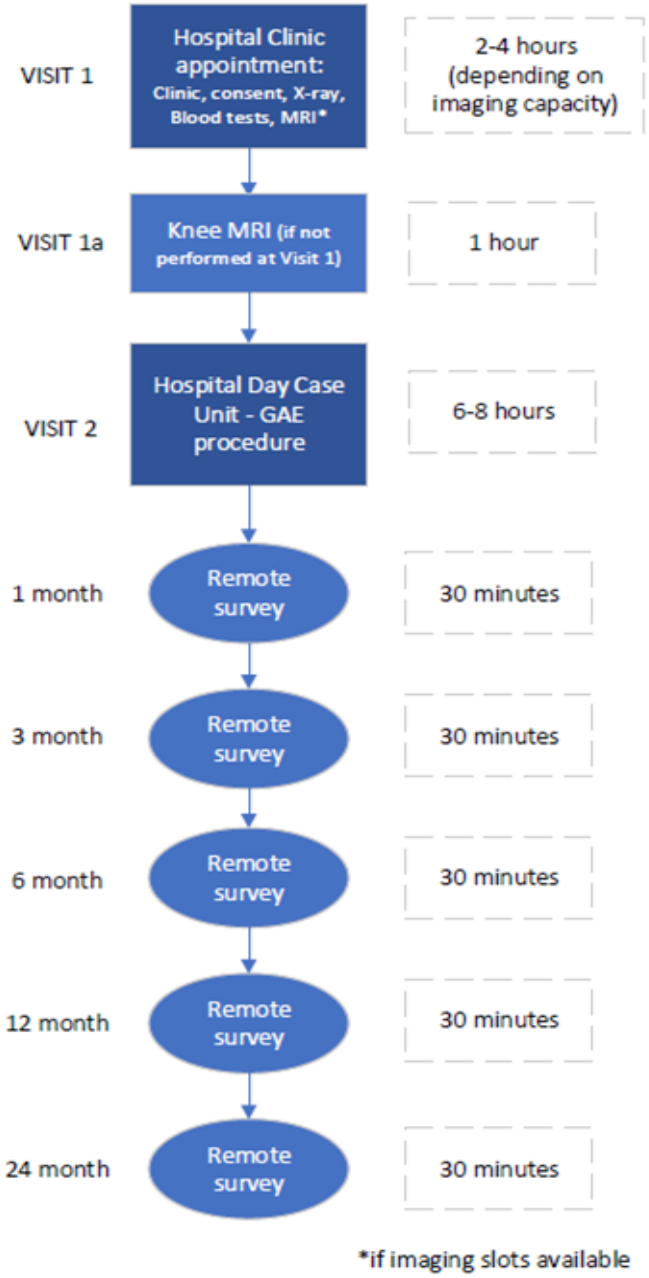
If included in the study, you will also undergo a Magnetic Resonance Imaging (MRI scan) of the knee to assess whether you have an increased amount of new bloods vessels on which to perform the procedure (referred to as target vessels). The MRI scan also allows detailed analysis of various parts of the knee to better understand the degree of OA.

The GAE procedure is done as a day case using local anaesthesia. A catheter is passed through an introducer sheath in the femoral artery (groin artery) and then angiography is performed by injecting radiology dye to identify the blood vessels (genicular arteries) supplying the area of increased new blood vessels. Once the new blood vessels arising from these arteries are identified, a smaller tube (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 and targeted embolization of the new blood vessels, importantly with preservation of the main genicular artery supplying the knee joint. As the presence of new blood vessels would have

been confirmed on the MRI scan, it is very unlikely that these are not seen at the time of GAE. Occasionally it is possible that the new blood vessels are not seen on the MRI scan and are only seen on the angiogram done at the time of the GAE procedure. If new blood vessels are not seen at the time of GAE either, the procedure will be considered technically unsuccessful.

The arterial access site in the groin is closed with manual compression and then you will be discharged home following a period of approximately four hours of observations.

Below is a flowchart which details the study events and expected amount of time taken at each event.



What happens on day of the procedure?

In the morning you will come to the Radiology Department reception on Floor 2 of the Grange University Hospital. You will be met by a member of the Interventional Radiology (IR) team who will then escort you to the IR Day Case Unit. There you will have routine checks such as blood pressure and heart rate. A radiology nurse will 'check you in'. You will be seen by the medical team who will once again go through the procedure. You with then be taken to the Interventional Radiology Suite, which is like an operating theatre with additional x-ray equipment. Doctors, nurses, radiographers and health care assistants will be present during the procedure. You will be awake throughout but may be given medication to help you relax. During the procedure, you will lie on the x-ray table, usually flat on your back. You may have a needle put into a vein in your arm so that the radiologist can give you a sedative or painkillers. You may have a monitoring device attached to your chest and finger, and you may be given oxygen through small tubes in your nose. The radiologist will keep everything as sterile as possible and will wear a theatre gown and operating gloves. The skin on your groin where the catheter is to be inserted will be cleaned with antiseptic and some local anaesthetic may be applied. The rest of your body (except your head) will be covered with a large sterile theatre sheet. The procedure will take approximately one hour. At the end of the procedure, the puncture wound in your groin will be closed either using a small dissolvable stitch, or by pressing on the artery for 10 minutes.

What happens immediately after the procedure?

You will initially go back to the day case area. You will need to lie flat for four hours and you will be regularly monitored for that duration. You will need someone to drive you home and someone to stay with you overnight. You should be able to walk and gently move around as soon as you are discharged but avoid strenuous activities for 48 hours.

Aftercare advice

You are not allowed to drive back home after the procedure and must be escorted home by an adult. Unfortunately, public transport or a taxi cannot be used for these purposes. There should also be an adult with you in the same household overnight following the procedure. Kindly let a team member know if this is not possible.

You will need to look out for signs of bleeding and/or infection at the entry site in the groin. You will have a dressing in place, which should be kept clean and dry for a couple of days. This can then be removed if the puncture wound appears to have healed/closed. If not, please apply a clean plaster until it has healed/closed. If you work, you will need five days off and you must not drive for five days following the procedure.

What are the possible benefits of taking part?

There are no guaranteed benefits of taking part. If the procedure is successful, the potential benefits of taking part in this study include:

1. Improvement in the symptoms (including pain) related to knee OA.

2. Reduction in need for regular pain medications or steroid injections and their associated side effects.

3. Improvement in mobility

4. Improvement in quality of life due to the above.

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.

However, please note that these benefits may not be achieved in all patients.

I have OA in both knees. Can I have both knees treated?

As part of the trial, only one knee can be treated. However, as mentioned above, if the procedure is widely adopted in the NHS Wales, this may be offered to you at that stage.

What are the possible disadvantages and risks of taking part?

MRI scan: MRI scan uses strong magnets to form detailed images of your knee. This scan requires you to place your lower body in the scanner. The scan itself takes about 20-30 minutes. Some patients may feel claustrophobic while in an MRI scanner. The MRI staff can always hear you and if feeling uncomfortable, you can request for the scan to be stopped at any time. The MRI also requires 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):

a. Pain: Mild pain at the groin access site is common after the procedure (approximately 1 in 5). This usually settles on its own or simple pain killers may help. If needed, you will be provided these medicines on discharge.
b. Bleeding (Less than 1 in 150): Minor bruising can happen at the site of arterial puncture in the groin. Post procedure manual groin compression is applied for 10 minutes and that reduces the risk of bleeding. Patients' medication history is carefully reviewed ahead of the procedure and all patients considered high risk of bleeding have their medication modified according to the established clinical practice or excluded from the study. Bleeding requiring surgery or transfusion is extremely rare.
c. Allergic reaction (less than 1 in 100): GAE also requires the use of a dye, contrast, to clearly look at the blood vessels. As with contrast agents used in MRI, there is a small risk of allergic reaction. You will be closely monitored during and following the procedure.
d. Blockage of an unintended blood vessel (referred to as non-target embolisation) (less than 1 in 100): Blockage of a blood vessel other than the intended vessel may result in damage to skin, muscle or other structures in the legs. As the procedure is done under X-ray control and by experienced operators, the risk of non-target vessel blockage is rare. You may notice signs of discolouration of the skin around the skin- do not apply ice to this.
e. Infection: there is risk of infection at the groin puncture site (less than 1 in 200) and at the vessel blockage site. You will be given antibiotics before the procedure and following the procedure to minimise this risk.
f. Disability (less than 1 in 200): there is a very rare risk of damage to the blood vessel causing compromise to the blood supply of the leg. This damage is exceedingly rare with experienced operators. If it were to happen it may require surgery. Risk of long-term disability is exceedingly rare.
g. Radiation:

   If you take part in this study, you will have a Genicular Artery Embolisation procedure & knee X-ray. 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 treatment. Ionising radiation may cause cancer many years or decades after the exposure.

We are all at risk of developing cancer during our lifetime. 50% of the population is likely to develop one of the many forms of cancer at some stage during our lifetime. Taking part in this study will add only a very small chance of this happening to you.

Long term safety implications of the procedure are currently not fully known. You will be followed up by the research team for a period of two years.

General risks of participating in a research study:

a. Data and confidentiality: All data will be handled in accordance with Health Board procedure and GDPR, mitigating any risks associated with confidentiality.
b. Completing the surveys may highlight emotions relating to quality of life. If any upset or distress is caused, please contact your GP or a member of the research team.

Why do I need blood tests and what happens to my blood sample?

Blood samples from all participants, who do not have relevant blood results available within the preceding 60 days, will be collected at the first clinic visit. This will include Full Blood Count (FBC) and Urea and Electrolytes (U and E). These are routine tests done prior to a patient receiving a contrast enhanced MRI or iodinated radiology dye and an interventional radiology procedure. The purpose is to ensure that it is safe to proceed with the tests and the GAE procedure.

All samples will be collected by the radiology preassessment team member who are fully trained to collect blood samples.

All samples will be collected, transported and analysed within the health board using established clinical pathways. All samples will be disposed of as per standard health board clinical practice once they have been analysed.

How will we use information about you?

We will need to use information from you and from your medical records for this research project. People will use this information to do the research or to check your records to make sure

that the research is being done properly. This information will be held by the research team and/ or the sponsor and will include:

- Name
- Contact Details
- Date of Birth
- NHS and/or Hospital Number

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.

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.

Information collected about you may also be used to support other research in future and may be shared anonymously with other researchers.

We will keep all information about you safe and secure.

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.
- If you choose to stop taking part in the study, we would like to continue collecting information about your health from central NHS records (the Welsh Clinical Portal), your hospital records (Aneurin Bevan Clinical Workstation and Radiology systems) and from your GP. If you do not want this to happen, tell us and we will stop.
- We need to manage your records in specific ways for the research to be reliable. This means that we won't be able to let you see or change the data we hold about you.

How will my information be kept confidential?

All information collected will be handled in line with the Data Protection Act (2018), on secure Health Board computers. Your data will be coded to provide an additional level of security, with only the research team having access to the identifiable data.

With your permission, we will inform your GP of your participation in this study, and details relating to your involvement in this study will also be documented in your medical records.

Where can you find out more about how your information is used?

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

- Sponsor Website: https://abuhb.nhs.wales/about-us/information-governance/
- Telephone: 01495 765019 or 01495 765085
- Email: infogov.abb@wales.nhs.uk

If you have a concern about any aspect of this study, in the first instance please discuss with a member of the research team.

If you wish to raise it with the sponsor, they can be contacted at: ABB.RandD@wales.nhs.uk

If you remain unhappy and wish to complain formally, you can contact The Information Commissioner's Office (ICO):

- Telephone helpline: 0303 123 1113
- Online Chat: https://ico.org.uk/global/contact-us/live-chat/

Do I have to take part in the study?

No. Participation in the study is entirely voluntary and it is up to you to decide if you want to take part or not. Taking part in the study, or not, is totally up to you. If you choose to withdraw from the study at any time, this will not affect the standard of care you receive, and you will continue to receive care and treatments as is usual practice.

If you consent to take part in the study, and withdraw prior to the GAE treatment, you simply will not receive the study procedure; and will continue to receive standard of care. If you choose to withdraw following the procedure, we will keep the information we have already collected about you and your treatment but will not collect any further follow-up information (trial questionnaires). If you choose to stop taking part in the study, we would like to continue collecting information about your health from central NHS records (the Welsh Clinical Portal), your hospital records (Aneurin

Bevan Clinical Workstation and Radiology systems) and from your GP. If you do not want this to happen, tell us and we will stop.

What will happen to the results of this study?

The results of this study will be fed back to the sponsor (ABUHB), the relevant clinical teams, the Health Board Executive team and the funders (Bevan Commission). All results will be anonymised, and no one will be able to identify participants from the report. The results may also be published in medical journals, presented at conferences and used to support future adoption of this procedure in the NHS.

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

This study has been developed alongside patients who, like you, have osteoarthritis of the knee. We have also worked with the charity Cymru Vs Arthritis in the design of our research, on behalf of the people of Wales.

Who has reviewed this study?

This study has been reviewed and approved by the local Health Board (ABUHB) as well as independent review and approval by the Leicester South Research Ethics Committee.

What if relevant new information becomes available?

If any information becomes available which is believed to be important to you or your involvement in the study, this will be communicated to you directly by a member of the research team, and your specialist doctor and/or GP where relevant.

What if something goes wrong?

If something were to not go as planned during or immediately after the GAE procedure, you would be taken care of as is usual clinical practice, by your hospital Doctor and their team.

If you feel something has gone wrong with the research study you can contact the researcher, the sponsor, or the independent patient liaison service (PALS contact).

If you remain unhappy and wish to complain formally, please contact the Putting Things Right Team.

- Email: Puttingthingsright.ABHB@wales.nhs.uk
- Telephone: 01495 745656.

In the event that 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 against the Aneurin Bevan University Health Board but you may have to pay your legal costs. The normal National Health Service complaints mechanisms will still be available to you.

Further information and useful contact details

	Telephone Number	Email/ Website
Lead Researcher Dr Nimit Goyal		Nimit.Goyal@wales.nhs.uk
Research Team at ABUHB		ABB.RandD@wales.nhs.uk
Sponsor Information Governance	01495 765019	infogov.abb@wales.nhs.uk
AB Putting things right team	01495 745656	Puttingthingsright.ABHB@wales.nhs.uk
ICO (Information Commissioner's Office)	0303 123 1113	https://ico.org.uk/global/contact-us/live-chat/
General advice on living with Osteoarthritis	08005200520	Cymru Vs Arthritis https://www.versusarthritis.org/in-your-area/wales/