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Study Title: GluePAE: Microsphere versus glue prostate artery embolisation for the treatment of benign prostate enlargement

Chief Investigator: Dr Clare Bent, Consultant Interventional Radiologist, University Hospitals Dorset NHS Foundation Trust

IRAS ID: 335518

REC Reference: 25/SC/0012

What is the purpose of the study?

An enlarged prostate can cause symptoms such as needing to urinate more urgently and more often, needing to urinate more at night, and being unable to control the flow of urine from the bladder.

Prostate Artery Embolisation (PAE) is one way of treating an enlarged prostate. This involves inserting a small tube into an artery in the groin or wrist until it reaches the artery that supplies the prostate, then injecting something to block it. This stops blood flowing to the prostate, which makes it shrink and relieves symptoms. This is usually done by injecting lots of small plastic balls called 'microspheres' and this is known to be effective in the short term. However, some patients find that symptoms come back later and may need more treatment.

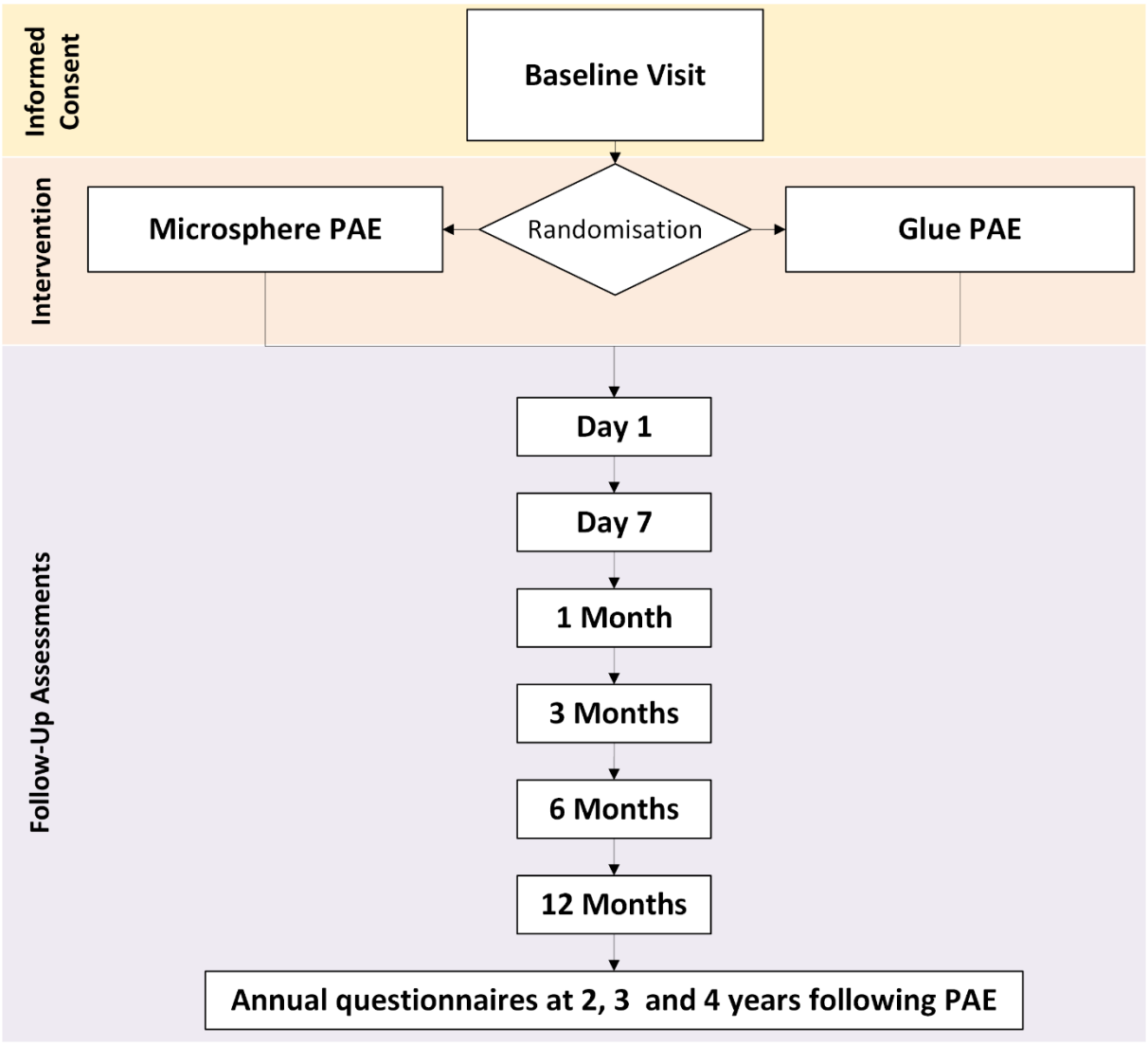
PAE can also be done using surgical glue instead of microspheres, which is a newer technique that may be more effective for longer. However, no studies have been done yet to confirm this.

This study aims to compare PAE using microspheres and glue to find out which is better in the longer term. We are working with [LOCAL SITE] and hospital sites across England who are experienced in offering PAE using both glue and microspheres to ensure our study participants receive high quality care.

Why have I been invited?

You have been invited to take part because you have an enlarged prostate and you have symptoms which would benefit from treatment with PAE.

Study Flowchart



Do I have to take part?

No – you can choose to join or not and if you do, you can withdraw at any time without affecting your medical care.

What will happen to me if I take part?

Consent

A member of the team will come and discuss the study with you, answer any questions you may have, and ask you to sign a consent form. At this point, you can also tell us if you would like a copy of the results of the study at the end. Copies of the consent form will be given to you and filed in your medical records.

Screening

As part of your routine care, you will have some tests to confirm that PAE is a suitable treatment, just as you would if you opted to have PAE outside of this study. We will ask you to have a physical examination, ask some questions about your medical history, and run tests to check that you are able to undergo PAE and take part in the study. One of these tests is a Computed Tomography (CT) scan. This is a type of scan which uses X-rays to create detailed pictures of your body. This scan helps us decide whether PAE would be suitable for you.

Randomisation

The use of microspheres or surgical glue during your PAE procedure will be decided at random. This ensures that each participant has an equal chance of receiving either treatment. Importantly, you will not know which treatment you will receive until after the study is complete as this may affect the results. This is known as 'blinding' and helps ensure that the results are as accurate and reliable as possible. Arrangements will be made for you to have the PAE procedure at [INSERT LOCAL SITE] within 8 weeks of this visit.

PAE Procedure and Follow-up Assessments

Once you have had the PAE treatment, we will ask you to complete questionnaires at 1 day, 7 days, 1 month, 3 months, 6 months after your treatment and then once a year until 4 years after your treatment. We will ask about your quality of life, pain levels, symptoms, and any other treatments you may have had.

These questionnaires may be completed face-to-face if they align with your normal appointments. Otherwise, we will ask you to complete these by post, phone or online based on your preference.

What are the possible disadvantages of taking part?

If you take part in this trial, the risks are similar to having your PAE as normal. Both microspheres and glue PAE are already in use within the NHS and the known risks are very small. These risks may include:

- your symptoms getting worse for the first 7-10 days after your PAE before improving,
- bruising where the tube went into your body (wrist or groin) that will resolve over time,
- temporary feeling of burning when passing urine which will pass over 7-10 days
- glue/microspheres moving to a different place in the body *This is called non target embolization and is rare but can result in injury to the bladder, bowel or penis – which, in the majority of cases, resolves on its own*

- Allergic response to iodinated contrast used during the procedure. This is unlikely to occur as involves the use of the same contrast used for the planning CT imaging

Prostate planning CT and a Prostate Artery Embolisation procedure are part of your routine care. If you take part in this study, you will not undergo any additional procedures. 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. The chances of this happening to you are the same whether you take part in this study or not.

What are the possible benefits of taking part?

While we cannot guarantee that this study will benefit you personally, the treatment you receive is likely to improve your condition and will help us to understand which is the best treatment to benefit future patients.

What if there is a problem?

If you have a concern about any aspect of this study, you should ask to speak to the researchers who will do their best to answer your questions or [*LOCAL SITE PI/SRN*] on [*LOCAL SITE CONTACT NUMBER*]**.** If you remain unhappy and wish to complain formally, you can do this through the hospital complaints procedure. Details can be obtained from the hospital Patient Advice and Liaison Service (PALS) on [*phone number*].

[*Add local R&D and Patient Advice & Liaison Service contact details*]

Harm

If something does go wrong and you are harmed during the study and this harm is due to negligence, then you may have grounds for legal action for compensation. The normal National Health Service complaints mechanisms will be available to you (if appropriate).

How will we use information about you?

We will need to use information from you for this research project. This information will include your:

- Name and/or initials
- Contact details (including email address)
- Date of Birth

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. University Hospitals Dorset NHS Foundation Trust is the sponsor of this research, and is responsible for looking after your information. We will keep all information about you safe and secure by:

- Storing your data in password-protected systems with restricted access.
- Ensuring that only authorized personnel involved in the research can access your data.
- Locking physical documents, such as signed consent forms, in secure filing cabinets within restricted-access offices

Your 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 a maximum of 10 years. The study data will then be fully anonymized and securely archived or destroyed.

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 your electronic patient record. If you do not want this to happen, tell us and we will stop

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 agree to take part in this study, you will have the option to take part in future research using your data saved from this study. [Insert details of any specific bank / repository]

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

You can find out more about how we use your information, including the specific mechanism used by us when transferring your personal data out of the UK.

our leaflet, available at www.hra.nhs.uk/patientdataandresearch

by asking one of the UHD Sponsorship team at researchsponsorship@uhd.nhs.uk

by sending an email to UHD Information Governance at information.governance@uhd.nhs, or

by ringing UHD Information Governance at 01202 303 626.

Will my taking part in the study be kept confidential?

Yes. All information which is collected about you during the course of the research will be kept strictly confidential. Any information about you which leaves the hospital

will have your name and any other personal identifiers removed, so that you cannot be recognised.

The only personally identifiable information collected will be from the registration form. This will only be accessible to members of the research team at UHD who have been granted permission to do so because they need this to contact you, via password protected accounts.

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

Yes, your GP will be informed to ensure they are aware of your involvement in the study.

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

You can find out more about how we use your information

- www.hra.nhs.uk/information-about-patients/
- https://www.uhd.nhs.uk/services/research-and-innovation/rbch/for-public-and-patients/protecting-your-data-in-research
- by asking one of the research team at your hospital
- by sending an email to Information.Governance@uhd.nhs.uk
- or by ringing the R&D team on 0300 019 8500.

University Hospitals Dorset NHS Foundation Trust will keep identifiable information about you from this study for no longer than required and a maximum of approximately 2 years after the study has finished. Should an 'early access programme' be planned we will contact you before the end of this period to confirm whether you would like your details to remain on file for this purpose.

What will happen if I do not carry on with the study?

You are free to withdraw at any time and this will have no impact on the ongoing care that you receive. You do not have to give a reason for withdrawal; however, we would be grateful for any feedback, which may help us to improve the study in the future.

If you choose to withdraw, we will use all information collected up to that point. If you no longer wish to receive results of the study, please let a member of the team know using the contact details on this page.

What will happen to the results of the research study?

The results of this study will help us find out which is the best treatment for patients.

The findings will be published in academic journals and presented at conferences. Importantly, no personal identifiable data will be shared with any external organisation/partner, nor in any publication.

If you would like to be informed of the results of the study, please indicate this on the registration form (including how). We will also share these on the University Hospitals Dorset Research and Development website and social media accounts for the study and organisations involved in the project.

Who is organising and funding the study?

This research is being led by Dr Clare Bent, a Consultant Interventional Radiologist at University Hospitals Dorset NHS Foundation Trust (UHD). Funding for this study has been provided by Guerbet LLC, a commercial company who manufacture surgical products commonly used in PAE. As 'Sponsor', UHD are responsible for managing the design, delivery, analysis and publication of the study, independently of Guerbet LLC. The funder will receive reports throughout the lifecycle of the research to monitor study progress and will be informed of the results at publication.

Conflicts of Interest

There is potential for a conflict of interest with Guerbet LLC both funding the study and being the manufacturer of another product used in the glue arm of the study. This has been considered by the Sponsor, who have taken steps to ensure this does not affect the study results. The study will be managed by University Hospitals Dorset NHS Foundation Trust independent of the funder.

Who has reviewed the study?

A 'Patient Advisory Group' has been set up for the project, involving people with lived experience of having treatment for an enlarged prostate. The group will help us to ensure that the study is designed with patients' needs and preferences in mind. They have reviewed the study design and documents, including this information sheet.

All research is reviewed by an independent group of people called a Research Ethics Committee, to protect the interests of study participants. This study has been reviewed and given a favourable opinion by the South Central - Oxford B Research Ethics Committee and approval by the Health Research Authority.

Further information and contact details:

If you have any questions, you can speak to one of the research team:

[INSERT CONTACT DETAILS FOR PI AND LOCAL RESEARCH TEAM]

Thank you for taking the time to read this information.