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A comparison of two treatments to reduce prostate size and symptoms in men with benign enlargement

Submission date
23/05/2025

Recruitment status
Recruiting

Registration date
27/05/2025

Overall study status
Ongoing

Last Edited
01/07/2025

Condition category
Urological and Genital Diseases

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

Plain English summary of protocol

Background and study aims
As men get older, it is common for the prostate to become enlarged. This condition is called benign prostate enlargement (BPE) and can cause symptoms such as needing to urinate more often, difficulty starting or stopping urination, or feeling like the bladder hasn't fully emptied. One way to treat BPE is a procedure called prostate artery embolisation (PAE), which works by blocking the blood supply to the prostate to help shrink it.
This study is testing whether a new type of medical glue works better or worse than the small plastic particles (called microspheres) currently used for this procedure. We want to find out if the glue gives similar symptom relief, is safe, and whether it may offer benefits such as shorter procedure times or longer-lasting results.

Who can participate?
Men aged 50 or over who have been diagnosed with BPE and referred for PAE by their NHS consultant may be invited to take part. Participants must meet specific criteria to ensure the treatment is suitable and safe. The study team will explain these in more detail at your clinic appointment.

What does the study involve?
Participants who join the study will be randomly assigned to receive one of two types of prostate artery embolisation (PAE) to help relieve urinary symptoms caused by benign prostate enlargement (BPE). One method uses small plastic particles (microspheres), which is the current standard treatment. The other uses a medical glue, which may work faster and provide longer-lasting benefits. Participants will not be told which treatment they receive. Before the procedure, participants will attend a clinic appointment where their medical history will be reviewed, standard health measurements will be taken, and questionnaires about urinary and sexual health will be completed. These questionnaires will be repeated at several points after the procedure to monitor progress.

The procedure involves inserting a small tube into an artery in the wrist or groin. The doctor will guide the tube to the blood vessels that supply the prostate and block them using either the

glue or microspheres, depending on the participant's group. After the procedure, participants will be followed up through a combination of clinic visits and remote check-ins for up to 4 years, with the most contact taking place in the first 6 months. Follow-up includes questionnaires (completed online or by phone) about symptoms and quality of life, and possibly scans at the hospital if these are part of usual care.

Participants are free to withdraw from the study at any time without it affecting their care. Any data collected up to that point will still be valuable for the study.

What are the possible benefits and risks of participating?
Participants may benefit from a reduction in urinary symptoms related to benign prostate enlargement (BPE), although this cannot be guaranteed. The information collected will help improve understanding of which treatment method offers the best outcomes for future patients.
Prostate artery embolisation (PAE) is a well-established procedure with known risks, which include pain at the access site, post-embolisation symptoms (such as fever, nausea, or pelvic discomfort), temporary difficulty urinating, urinary tract infections (UTIs), or blood in the urine. More serious complications are rare, but all participants will be monitored closely. The glue being tested is already used safely in other procedures, but using it for PAE is a more recent idea and not as well established as PAE using microspheres.
Where is the study run from?
The study is sponsored by University Hospitals Dorset NHS Foundation Trust and delivered with support from Dorset Clinical Trials Unit, a specialist function embedded within UHD's R&D team.

When is the study starting and how long is it expected to run for?
The study expects to start recruiting patients in early June 2025 and will continue recruiting into early 2026, with each participant taking part for up to 4 years after their treatment.

Who is funding the study?
Principal funding for this study is provided by Guerbet LLC, a company that manufactures the embolic liquid used in the study. Additional funding is provided by the British Society of Interventional Radiology (BSIR) to support collection of extra research data. Neither funder is involved in the day-to-day running of the trial.

Who is the main contact?
Participants and healthcare professionals can contact the study team at:
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Clinical Trials Unit Project Manager, Dorset Clinical Trials Unit
University Hospitals Dorset NHS Foundation Trust
Email: dorsetctu@uhd.nhs.uk

Contact information

Type(s)
Principal Investigator

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Type(s)
Public, Scientific

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Additional identifiers

EudraCT/CTIS number
Nil known

IRAS number
335518

ClinicalTrials.gov number
Nil known

Secondary identifying numbers
CPMS 59007

Study information

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

Acronym
GluePAE

Study objectives
This research aims to evaluate whether glue prostate artery embolization (PAE) offers a more efficient and durable treatment option for men with BPE than microsphere PAE.

Ethics approval required
Ethics approval required

Ethics approval(s)
Approved 11/02/2025, South Central - Oxford B Research Ethics Committee (2 Redman Place, Stratford, London, E20 1JQ, United Kingdom; +44 207 104 8019; oxfordb.rec@hra.nhs.uk), ref: 25/SC/0012

Study design
Interventional randomized controlled trial

Primary study design
Interventional

Secondary study design
Randomised controlled trial

Study setting(s)
Other

Study type(s)
Treatment

Participant information sheet
See study outputs table

Health condition(s) or problem(s) studied
Prostate artery embolization

Interventions
If a person chooses to take part, they will be asked to provide informed consent and undergo a baseline assessment. The baseline assessment includes a review of their medical history and the collection of data from routine tests used to confirm their eligibility for the intervention as standard of care.

During the baseline assessment, participants will be asked about their symptoms, including their levels of pain and how their daily activities are affected. They will also complete questionnaires regarding their quality of life and any other treatments they have received for BPE.

Once the baseline assessment is complete, participants will be randomly assigned to one of two groups: one group will receive the traditional PAE using microspheres, while the other group will receive the glue-based PAE. Both procedures will be performed under local anaesthesia, with or without intravenous sedation depending on patient need, and participants will be monitored for any immediate side effects afterward.

After the treatment, participants will be followed up at regular intervals: 1 day, 1 week, 1 month, 3 months, 6 months, and then annually for up to 4 years. During these follow-up assessments,

they will be asked about their symptoms and overall health through questionnaires, and may undergo additional tests, such as ultrasound or MRI scans, according to routine care at each participating site.

Throughout the study, all information collected will be kept confidential, and participants will be informed that they can withdraw from the study at any time. The findings will help determine if the glue-based PAE technique is a safe and effective alternative to microsphere-based PAE for managing BPE symptoms.

Intervention Type
Procedure/Surgery

Primary outcome measure
1. Lower urinary tract symptoms are measured using the International Prostate Symptom Score (IPSS) questionnaire at Baseline, Day 0 (Procedure), 1 Month, 3 Months, 6 Months, 1 Year, 2 Years, 3 Years, and 4 Years
2. Erectile function is measured using the International Index of Erectile Function (IIEF) questionnaire at Baseline, Day 0 (Procedure), 1 Month, 3 Months, 6 Months, 1 Year, 2 Years, 3 Years, and 4 Years
3. Ejaculatory bother is measured using the MSHQ-EjD Ejaculation Bother Score questionnaire at Baseline, Day 0 (Procedure), 1 Month, 3 Months, 6 Months, 1 Year, 2 Years, 3 Years, and 4 Years
4. Quality of life is measured using a Quality of Life questionnaire at Baseline, Day 0 (Procedure), Day 1, Day 7, 1 Month, 3 Months, 6 Months, 1 Year, 2 Years, 3 Years, and 4 Years
5. Procedural satisfaction is measured using a Procedural Satisfaction Score questionnaire at Day 7
6. Pain is measured using a Pain Score questionnaire at Day 1, Day 7, 1 Month, 3 Months, and 6 Months
7. Post-embolisation syndrome symptoms are measured using a Post Embolisation Syndrome questionnaire at Day 0 (Procedure), Day 1, Day 7, 1 Month, and 3 Months
8. Presence of urinary tract infection is measured using a questionnaire at Day 0 (Procedure), Day 1, Day 7, 1 Month, 3 Months, 6 Months, 1 Year, 2 Years, 3 Years, and 4 Years
9. Presence of catheter and time to removal are measured using a questionnaire at Day 0 (Procedure), Day 1, Day 7, 1 Month, 3 Months, 6 Months, 1 Year, 2 Years, 3 Years, and 4 Years
10. Use of additional BPE-related LUTS treatments is measured using a questionnaire at Day 0 (Procedure), 1 Month, 3 Months, 6 Months, 1 Year, 2 Years, 3 Years, and 4 Years
11. Recurrent symptoms are measured using a questionnaire at 1 Month, 3 Months, 6 Months, 1 Year, 2 Years, 3 Years, and 4 Years
12. Hospital admissions are measured using hospital records at Day 0 (Procedure), Day 1, Day 7, 1 Month, 3 Months, 6 Months, 1 Year, 2 Years, 3 Years, and 4 Years
13. Adverse events are measured using clinical assessment and patient report at Day 0 (Procedure), Day 1, Day 7, 1 Month, 3 Months, 6 Months, 1 Year, 2 Years, 3 Years, and 4 Years
14. Concomitant medication use is measured using a medication check at Baseline, Day 0 (Procedure), Day 1, Day 7, 1 Month, 3 Months, 6 Months, 1 Year, 2 Years, 3 Years, and 4 Years
15. Prostate anatomical features are measured using CTA imaging at Baseline
16. Procedural characteristics are measured using procedural data (procedure duration, technical data) at Day 0 (Procedure)
17. Radiation exposure is measured using radiation dose data at Day 0 (Procedure)

Secondary outcome measures
There are no secondary outcome measures

Overall study start date
07/06/2023

Completion date
03/03/2030

Eligibility

Key inclusion criteria
1. Men > 18 years of age
2. Patients with diagnosed BPE-related LUTS
3. Moderate to severe symptoms of BPE-related LUTS

Participant type(s)
Patient

Age group
Adult

Lower age limit
18 Years

Sex
Male

Target number of participants
Planned Sample Size: 300; UK Sample Size: 300

Key exclusion criteria
1. Prior surgical BPE treatment including invasive therapy or minimally invasive surgical therapies (MISTs) in the past 12 months
2. Currently using a urinary catheter, either indwelling or intermittent self-catheterisation
3. Suspicion of clinically significant prostate cancer, defined as a Gleason score of ≥7, a tumour volume of ≥0.5cc, or the presence of extraprostatic extension
4. Arterial anatomy preventing pelvic angiography
5. Contraindication to intravascular iodinated contrast, such as allergies or severely elevated creatinine/renal failure
6. History of urethral stricture or its treatment
7. Known or suspected neurogenic bladder dysfunction
8. Uncorrected coagulopathy
9. Allergy to microsphere or glue embolic materials
10. Lacks capacity to consent to the study or comply with the requirements of the study procedures and assessments
11. Participants who are unable to read, speak, or understand English sufficiently to comply with study assessments or provide informed consent

Date of first enrolment
02/06/2025

Date of final enrolment

03/03/2026

Locations

Countries of recruitment
England

United Kingdom

Study participating centre
University Hospitals Dorset NHS Foundation Trust
Management Offices
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United Kingdom
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Study participating centre
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Southampton General Hospital
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Study participating centre
Royal Berkshire NHS Foundation Trust
Royal Berkshire Hospital
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Study participating centre
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Study participating centre
Guys and St Thomas' NHS Foundation Trust
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Study participating centre
Imperial College Healthcare NHS Trust
The Bays
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South Wharf Road
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W2 1BL

Study participating centre
University College London Hospitals NHS Foundation Trust
250 Euston Road
London
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NW1 2PG

Study participating centre
Manchester University NHS Foundation Trust
Cobbett House
Oxford Road
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M13 9WL

Study participating centre
North Bristol NHS Trust
Southmead Hospital
Southmead Road
Westbury-on-trym
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BS10 5NB

Study participating centre
University Hospitals Birmingham NHS Foundation Trust
Queen Elizabeth Hospital
Mindelsohn Way
Edgbaston
Birmingham
United Kingdom
B15 2GW

Study participating centre
The Christie NHS Foundation Trust
550 Wilmslow Road
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Sponsor information

Organisation
University Hospitals Dorset NHS Foundation Trust

Sponsor details
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Sponsor type
Hospital/treatment centre

Website
https://www.uhd.nhs.uk

ROR
https://ror.org/02pa0cy79

Funder(s)

Funder type

Industry

Funder Name
Guerbet

Alternative Name(s)
Guerbet LLC, Guerbet, LLC

Funding Body Type
Private sector organisation

Funding Body Subtype
For-profit companies (industry)

Location
United States of America

Funder Name
British Society of Interventional Radiology

Results and Publications

Publication and dissemination plan
We plan to disseminate our findings via high impact journals, conference presentations and a more public focussed dissemination activity for participants and members of the public.

Intention to publish date

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?
Participant information sheet	version 1.1	28/01/2025	23/05/2025	No	Yes