ISRCTN50571778 https://doi.org/10.1186/ISRCTN50571778

# PREMISE: a surgical trial of minimally invasive treatments of prostate obstruction of the bladder

**Submission date**
27/03/2023

**Recruitment status**
Recruiting

**Registration date**
10/05/2023

**Overall study status**
Ongoing

**Last Edited**
08/08/2025

**Condition category**
Surgery

[ ] 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
Benign prostate enlargement (BPE) with ageing causes increasing bladder outlet obstruction (BOO), a situation known as benign prostatic obstruction (BPO). BPO is a major contributor to the emergence of lower urinary tract symptoms (LUTS). Voiding symptoms (e.g. slow stream, intermittency, hesitancy, straining, dribbling) and post voiding symptoms (e.g. post-micturition dribble) reflect problems occurring when passing urine or immediately after. Many men also experience storage symptoms (e.g. increased daytime urinary frequency, nocturia, urgency, incontinence). The most severe situation as BOO progresses is acute urinary retention, when a man becomes unable to pass urine at all, leading to painful bladder distension which requires emergency treatment with an indwelling catheter (IDC) to relieve the physical blockage until definitive treatment can be undertaken.
There are several types of surgery currently available for treatment of benign prostate enlargement. They all have different benefits and negatives, so we currently don't know which type of surgery is best.
Transurethral resection of the prostate (TURP) has been the main surgery performed for treatment of benign prostate enlargement for a number of years, it is known to be effective and is a widespread and standardised procedure. This surgery requires a general anaesthetic and usually a 1 to 3 day hospital stay. More recently, a number of alternative minimally invasive surgeries have become available. These usually require a shorter time in hospital and potentially a lower risk of complications.
PREMISE will compare TURP with three other minimally invasive surgeries currently used in NHS practice (Rezum Water Vapour Therapy, Prostatic Urethral Lift and iTIND) to see which is most effective at treating symptoms caused by benign prostate enlargement, in order to inform future care within the NHS.

Who can participate?
Men aged 50 years or over who are eligible for surgical treatment of benign prostate enlargement.

What does the study involve?
There are several types of procedure currently available for treatment of benign prostate enlargement causing bothersome urinary symptoms. The PREMISE trial will compare 4 different procedures currently available within the NHS to see how effective they are at treating the symptoms associated with benign prostate enlargement. The trial will also investigate whether the procedures offer value for money to both the NHS and patients.
Transurethral resection of the prostate (TURP) is a surgical procedure that involves cutting away a section of the prostate. It is known to be effective and is a widespread and standardised procedure performed for the treatment of symptoms of benign prostate enlargement. More recently, a number of alternative minimally invasive procedures have become available. These usually require a shorter time in hospital and potentially have a lower risk of complications and long term side effects. This study hopes to confirm whether they are as effective in treating symptoms caused by benign prostate enlargement as the main treatment, TURP.
If a participant agrees to take part in the study, following informed consent, an initial screening appointment will take place. The participant will be randomly allocated (by a computer) to have one of the 4 procedures. The participant and their doctor will not get to choose which of the treatments the participant is allocated to. Taking part in the trial will involve an extra hospital visit 1 year after treatment, as well as an additional telephone appointment 6 weeks and 6 months after treatment. The participant will also need to fill in some brief questionnaires about their allocated procedure and then again at 6 weeks, 6 months, 1 year, 2 years and 3 years after treatment. These can be completed on line or on paper.

What are the possible benefits and risks of participating?
TURP surgery requires a general anaesthetic and usually a 1 to 3 day hospital stay and you will need a catheter in place after the operation. In most cases,
TURP is a safe procedure and the risk of serious complications is small. But many men who have a TURP lose the ability to ejaculate semen, although they still have physical pleasure from ejaculation (orgasm). Some men also lose the ability to control their bladder (urinary incontinence), although this usually passes in a few weeks but in rare cases, it may be persistent and need further treatment. There's also a small risk of problems such as erectile dysfunction, bleeding, difficulties passing urine and urinary tract infections (UTIs).

REZUM surgery is usually performed under sedation or general anaesthesia and takes less than 10 minutes to complete and you are usually able to go home on the same day but you will need a catheter in place. The operation can cause bleeding and UTIs after the procedure are not uncommon, as well as discomfort passing urine. It does take up to 3 months to notice an improvement in symptoms. This is not the case with some of the other options where the improvement is often noticed within the first few days after catheter removal. Sexual side effects and urinary incontinence are not commonly seen after this procedure.

Prostatic Urethral Lift (Urolift) takes 10-15 minutes to complete and patients are normally able to go home the same day. It is generally performed under local anaesthesia or spinal/general anaesthesia. You do not usually need to have a catheter put in after this procedure. You are likely to have some pain on passing urine, pelvic discomfort and frequent urination for a few weeks after the procedure. The implants are permanent and can affect the diagnostic quality of MRI scanning of the prostate if needed in the future, although you can still have an MRI scan. Sexual side effects are not commonly seen after this procedure.

Temporary Implantable Nitinol Device (iTIND) procedure is done as a day-case procedure under sedation, spinal anaesthetic or general anaesthetic. It is removed after 5-7 days under local anaesthesia and without the need for a catheter.
Some men find the iTIND implant uncomfortable, but these symptoms usually disappear within a

day or two of the device being removed. Sexual side effects are not commonly seen after this procedure.

Where is the study run from?
Newcastle upon Tyne Hospitals NHS Foundation Trust (UK)

When is the study starting and how long is it expected to run for?
April 2022 to December 2028

Who is funding the study?
National Institute for Health and Care Research (NIHR) (UK).

Who is the main contact?
PREMISE@newcastle.ac.uk

### Study website
http://www.premisetrial.co.uk

# Contact information

### Type(s)
Scientific

### Contact name
Dr PREMISE Trial Manager

### Contact details
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# Additional identifiers

### EudraCT/CTIS number
Nil known

### IRAS number
318198

### ClinicalTrials.gov number
Nil known

### Secondary identifying numbers
CPMS 55332, NIHR131984, IRAS 318198

# Study information

## Scientific Title
A randomised controlled trial of minimally invasive surgical treatments for bladder outlet obstruction due to enlarged prostate in the National Health Service

## Acronym
PREMISE

## Study objectives
The trial will evaluate and make recommendations for use of innovative minimally invasive treatments of prostate obstructions of the bladder in comparison to current standard of care practice (TURP, trans urethral resection of the prostate). The results will inform NICE, other guidelines and policy makers.

## Ethics approval required
Old ethics approval format

## Ethics approval(s)
Approved 30/03/2023, North West - Preston Research Ethics Committee (Barlow House, 3rd Floor, 4 Minshull Street, Manchester, M1 3DZ, UK; +44 207 104 8019; preston.rec@hra.nhs.uk), ref: 23/NW/0053

## Study design
Interventional randomized controlled trial

## Primary study design
Interventional

## Secondary study design
Randomised controlled trial

## Study setting(s)
Hospital

## Study type(s)
Treatment

## Participant information sheet
Please contact your local urology team for details of your nearest local site participating in the study

## Health condition(s) or problem(s) studied
Minimally invasive surgical treatments for bladder outlet obstruction due to enlarged prostate

## Interventions
PREMISE is a multi-arm, multi centre, randomised controlled trial that will take place over 10 different sites/Urology Area Networks.

PREMISE is looking at the clinical and cost effectiveness of different treatments in patients with bladder outlet obstruction due to enlarged prostate. 536 participants will be randomised to receive one of the 4 treatment options:

Prostatic urethral lift (Urolift) vs Temporary Implantable Nitinol Device (iTIND) vs Water vapour ablation (Rezum) vs Transurethral resection of prostate (TURP).

Potential patients within secondary care will be identified through dedicated Lower Urinary Tract Symptoms (LUTS) clinics and general urology clinics, as well as through database searches for patients already waiting to receive standard of care treatment. Potential patients will be screened and if eligible and willing to take part, they will be consented onto the trial. Trial participants will then be randomised to receive either TURP or one of the 3 minimally invasive procedures.

As part of the trial the participant will have a number of clinical procedures performed and will complete questionnaires at various timepoints throughout the study. Participants will be given the option of completing the study questionnaires on paper and returning them in a pre-paid, addressed envelope, or completing them electronically. Consent will be sought from participants to be contacted by post, telephone, email and text message for the purposes of trial communication and completion of the study questionnaires.

At the screening visit, following the participant giving consent to take part in the trial, demographic and medical history information will be taken, along with details of medications that the participant is currently taking. The following procedures may also be performed if they have not previously been performed as part of standard of care within the defined time period stated in the protocol; Prostate Ultrasound, Digital Rectal Exam and Flow test and post-void residual scan. If the participant meets all of the eligibility criteria, they will complete their first set of study questionnaires, before being randomised to 1 of the 4 possible study interventions. If a screening Flow test and post void residual scan is required this can either be completed at the end of the screening visit once eligibility has been confirmed (if this is convenient for both the patient and research team), or at a separate visit before the procedure if more convenient.

In the event that the time between completing the screening set of questionnaires and receiving the intervention is greater than 6 months, the questionnaires will need to be repeated at a remote baseline visit, within 3 months prior to the procedure.

The participant will then attend for their allocated treatment at a hospital within their Urology Area Network / at their local site and will undergo post-procedural follow-up as per standard of care.

The trial specific follow-up is comprised of a telephone visit with the local study research team at 6 weeks and 6 months post-treatment, an on-site visit with the local study research team at 1 year post-treatment and a remote visit at 2 and 3 years post-treatment.
The completion of various study questionnaires will also be required at the 6 Weeks, 6 Months, 1 year, 2 Years and 3 Years post-treatment visits.

The 6 weeks and 6 months post-treatment telephone visits will comprise a discussion with their local research team of any side effects the participant has experienced since their treatment which are deemed to be possibly associated with either the treatment, the patient's benign prostate enlargement, a progression of their condition, or treatment failure. The participant will also be asked for details of any medications that they have taken for any of the conditions described above, as well as details of:
1. The dates/duration and frequency of any episodes of catheterisation since treatment.
2. Whether they have needed any blood products, e.g., blood transfusions since treatment.
3. The length of their initial hospital stay following their treatment.
4. Whether they have had any episodes of acute urinary retention.

The 1 Year post-treatment visit will be an on-site visit where the participant will undergo a Flow test and post-void residual scan. They will also be asked for details of any additional episodes of catheterisation and any additional incidents of acute urinary retention.

The 2 Years and 3 Years post-treatment visits will be completed remotely as these visits are only composed of the completion of the study questionnaires.

## Intervention Type
Procedure/Surgery

## Primary outcome measure
1. Clinical effectiveness of treatments measured using change in international prostate symptom score (I-PSS) from baseline to 12 months post-intervention

Primary economic outcome measure:
2. Cost-effectiveness of treatments measured using incremental cost per quality-adjusted life year (QALY) gained at 12 months post-intervention.
2.1. Cost-effectiveness acceptability curves (CEACs) to assess the probability of each of the interventions being considered cost-effective at different willingness-to-pay (WTP) thresholds for a gained QALY
2.2. QALYs will be calculated using responses to the EQ-5D-5L questionnaire

## Secondary outcome measures
1. Impact on bladder voiding efficiency (BVE) and maximum flow rate (Qmax) measured using change from baseline to 12 months post-intervention in Post void residual and Maximum flow rate (Qmax)
2. Adverse events up to six months post-intervention collected via Operative parameters and Adverse event review at six weeks and six months post-intervention
3. Incontinence measured using International Consultation on Incontinence Questionnaire Male Lower Urinary Tract Symptoms Module (ICIQ-MLUTS) at baseline, six months, 12 months, two and three years post-intervention
4. Sexual function measured using ICIQ-MLUTSsex at baseline, six months, 12 months, two and three years post-intervention
5. Quality of life and general health measured using:
5.1. I-PSS-QOL at baseline, six months, 12 months, two and three years post-intervention
5.2. ICIQ-LUTSqol at baseline, six months, 12 months, two and three years post-intervention
5.3. EQ-5D-5L at baseline, six weeks post-intervention, six months, 12 months, two and three years post-intervention
6. Length of post-intervention hospital stay measured using patient records
7. Use of perioperative and post-intervention catheterisation duration and subsequent use of catheters up to three years post-intervention measured using patient records
8. Number of hospital attendances (in patient or outpatient visits) for events/conditions possibly associated with BPE, condition progression, intervention, (including routine follow-up appointments post-intervention) or treatment failure up to 12 months post-intervention
9. Number of patients requiring blood transfusions up to six weeks post-intervention measured using patient records
10. Number of patients experiencing post-intervention acute urinary retention up to 12 months post-intervention measured using patient records

Secondary economic outcome measures:
11. Costs and quality of life following intervention over 12 months:

11.1. Average healthcare costs per participant over 12 months post-intervention for each area of resource use
11.2. Utility scores derived from responses to the EQ-5D-5L questionnaire at baseline, six weeks post-intervention, six and 12 months post-intervention
11.3. Average QALYs per participant at 12 months post-intervention
12. Cost effectiveness of the interventions at two years and three years post-intervention:
12.1. Incremental cost per quality-adjusted life year (QALY) gained at two and three years post-intervention
12.2. Cost- effectiveness acceptability curves to assess the probability of each of the interventions being considered cost-effective at different WTP thresholds for a gained QALY at two and three years post-intervention
13. Model costs and quality of life over a patient's lifetime
14. Model the incremental cost per QALY over the patient's lifetime using ICERs and CEACs derived by extrapolating costs and QALYs from the data observed during the trial
15. Estimate net benefit value of the interventions for each individual using:
15.1. Participants' willingness to pay for each intervention or combination of interventions
15.2. Incremental net benefit of interventions

Exploratory outcome measure:
16. Assess carbon footprint of each intervention and its associated pathway

### Overall study start date
01/04/2022

### Completion date
31/12/2028

# Eligibility

### Key inclusion criteria
Current inclusion criteria as of 08/08/2025:

1. Men aged 50 years or over
2. Prostate volume of between 30ml ($cm^3$) and up to and including 80ml ($cm^3$) measured by ultrasound or cross-sectional scan
3. Eligible for surgery for presumed Bladder Outlet Obstruction with an NHS setting
4. Willing and able to comply with trial procedures, visit schedules, trial restrictions and requirements.
5. Willing and able to provide informed consent.

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Previous inclusion criteria:

1. Men aged 50 years or over
2. Prostate volume up to 80cc (measured by ultrasound or cross-sectional scan)
3. Eligible for surgery for presumed Bladder Outlet Obstruction with an NHS setting
4. Willing and able to comply with trial procedures, visit schedules, trial restrictions and requirements.
5. Willing and able to provide informed consent.

### Participant type(s)
Patient

### Age group
Adult

### Lower age limit
50 Years

### Sex
Male

### Target number of participants
Planned Sample Size: 536; UK Sample Size: 536

### Key exclusion criteria
1. Any known or suspected prostate cancer treated or untreated; (If known) PSA > = 0.15
2. Known or suspected neuropathic bladder dysfunction
3. Any previous minimally invasive or surgical treatment to the prostate or bladder outlet.
4. Contraindication for both spinal and general anaesthesia
5. Catheterised or self catheterising
6. Predicted life expectancy less than 3 years
7. Participation in any other current interventional trial

### Date of first enrolment
01/05/2023

### Date of final enrolment
28/02/2026

## Locations

### Countries of recruitment
England

Scotland

United Kingdom

Wales

### Study participating centre
**The Newcastle upon Tyne Hospitals NHS Foundation Trust**
Freeman Hospital
Freeman Road
High Heaton
Newcastle upon Tyne
United Kingdom
NE7 7DN

**Study participating centre**
**Imperial College Healthcare NHS Trust**
The Bays
St Marys Hospital
South Wharf Road
London
United Kingdom
W2 1BL

**Study participating centre**
**Hampshire Hospitals NHS Foundation Trust**
Basingstoke and North Hampshire Hos
Aldermaston Road
Basingstoke
United Kingdom
RG24 9NA

**Study participating centre**
**Norfolk and Norwich University Hospitals NHS Foundation Trust**
Colney Lane
Colney
Norwich
United Kingdom
NR4 7UY

**Study participating centre**
**NHS Fife**
Hayfield House
Hayfield Road
Kirkcaldy
United Kingdom
KY2 5AH

**Study participating centre**
**Cambridge University Hospitals NHS Foundation Trust**
Cambridge Biomedical Campus
Hills Road
Cambridge
United Kingdom
CB2 0QQ

**Study participating centre**
**Frimley Health NHS Foundation Trust**
Portsmouth Road
Frimley
Camberley
United Kingdom
GU16 7UJ

**Study participating centre**
**Airedale NHS Trust**
Airedale General Hospital
Skipton Road
Steeton
Keighley
United Kingdom
BD20 6TD

**Study participating centre**
**Bolton NHS Foundation Trust**
The Royal Bolton Hospital
Minerva Road
Farnworth
Bolton
United Kingdom
BL4 0JR

**Study participating centre**
**Sandwell and West Birmingham Hospitals NHS Trust**
Midland Metropolitan University Hos
Grove Lane
Smethwick
United Kingdom
B66 2QT

**Study participating centre**
**Liverpool University Hospitals NHS Foundation Trust**
Royal Liverpool University Hospital
Prescot Street
Liverpool
United Kingdom
L7 8XP

### Study participating centre
**North West London Hospitals NHS Trust**
Northwick Park Hospital
Watford Road
Harrow
United Kingdom
HA1 3UJ

### Study participating centre
**Salisbury NHS Foundation Trust (uhs)**
Salisbury District Hospital
Odstock Road
Salisbury
United Kingdom
SP2 8BJ

## Sponsor information

### Organisation
Newcastle upon Tyne Hospitals NHS Foundation Trust

### Sponsor details
Freeman Hospital
Freeman Road
High Heaton
Newcastle-upon-Tyne
England
United Kingdom
NE7 7DN
+44 1912825959
tnu-tr.sponsormanagement@nhs.net

### Sponsor type
Hospital/treatment centre

### Website
http://www.newcastle-hospitals.org.uk/

### ROR
https://ror.org/05p40t847

# Funder(s)

### Funder type
Government

### Funder Name
NIHR Evaluation, Trials and Studies Co-ordinating Centre (NETSCC)

# Results and Publications

### Publication and dissemination plan
Planned publication in a high-impact peer-reviewed journal

### Intention to publish date
28/02/2029

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

### IPD sharing plan summary
Data sharing statement to be made available at a later date

### Study outputs

| Output type | Details | Date created | Date added | Peer reviewed? | Patient-facing? |
|---|---|---|---|---|---|
| HRA research summary | | | 20/09/2023 | No | No |