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UNBLOCS: UriNary oBstruction relieved by Laser Or Conventional Surgery

Submission date
16/09/2013

Recruitment status
No longer recruiting

Registration date
20/09/2013

Overall study status
Completed

Last Edited
08/02/2021

Condition category
Urological and Genital Diseases

[X] Prospectively registered
[X] Protocol
[_] Statistical analysis plan
[X] Results
[_] Individual participant data

Plain English summary of protocol
Background and study aims
The prostate gland sits at the exit of the bladder like a collar so when it enlarges it can be difficult, or even impossible, to pass urine, which can cause men significant problems and result in hospital admissions. 25,000 men each year have an operation to relieve this problem, making it one of the most common operations performed in the NHS. Transurethral resection of the prostate (TURP) is the standard operation and is generally a very successful procedure, although it does have some complications. Various laser procedures have been tried as their use leads to less blood loss and a faster return home. However, they have not become widely used, either because they have been difficult to do or because the results were not as good as TURP. We now have the opportunity to use a new type of laser called thulium which cuts and vaporises the prostate and has shown promising results in a small study.

Who can participate?
Men who are fit to have prostate surgery for either bothersome lower urinary tract symptoms (LUTS) or urinary retention, secondary to benign prostatic obstruction (BPO).

What does the study involve?
Men who need a prostate operation are randomly allocated to either have the thulium operation or TURP. We want to know if the thulium operation is as good as TURP, including whether patients benefit by having less bleeding and going home earlier, and if the cost of the operation is less. We expect that most patients will have the operation as a day case and not stay overnight at the hospital. The success of the two procedures will be mainly judged by a simple symptom questionnaire completed by men and measurement of the speed at which patients pass urine before and after surgery.

What are the possible benefits and risks of participating?
There may be no direct benefit to men who take part, but they will be helping with this research enabling doctors to assess which operation is best and safest. The men will receive considerably more post-operative follow-up than is available routinely and this should ensure that men receive optimum care. The benefit to men, the NHS and society is that at the end of the trial, it

will be known which operation is most cost-effective. The risks are that they may have a less effective operation, but any operation carries a risk, and it is not known which of the two procedures is more effective or more risky.

Where is the study run from?
This study is run from North Bristol NHS Trust in collaboration with the clinical trials unit at the University of Bristol, UK. There will be six centres across the UK participating in the trial. Urology departments in the following centres: North Bristol NHS Trust (lead centre), The Newcastle Upon Tyne Hospitals NHS Foundation Trust, NHS Grampian, Great Western Hospital NHS Foundation Trust, Royal United Hospital Bath NHS Trust, Gloucestershire Hospitals NHS Foundation Trust

When is the study starting and how long is it expected to run for?
Recruitment will start in early 2014 and the study will end in December 2017

Who is funding the study?
National Institute for Health Research, Health Technology Assessment (UK)

Who is the main contact?
The co-ordinating trial office - Bristol Randomised Trials Collaboration (BRTC)

Contact information

Type(s)
Scientific

Contact name
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Additional identifiers

EudraCT/CTIS number

IRAS number

ClinicalTrials.gov number

Secondary identifying numbers
HTA 12/35/15

Study information

Scientific Title
A randomised controlled trial to determine the clinical and cost effectiveness of thulium laser transurethral vaporesection of the prostate (ThuVARP) versus transurethral resection of the prostate (TURP) in the National Health Service (NHS)

Acronym
UNBLOCS

Study objectives
The key aim of this research is to determine whether thulium laser transurethral vaporesection of the prostate (ThuVARP) is equivalent to transurethral resection of the prostate (TURP) in men with benign prostatic obstruction (BPO) treated within the NHS, judged on a patient reported symptom severity score (IPSS) and the maximum urine flow rate (Qmax).

Ethics approval required
Old ethics approval format

Ethics approval(s)
National Research Ethics Service (NRES) Committee South West - Frenchay, 15/01/2014

Study design
Randomised controlled parallel-group trial

Primary study design
Interventional

Secondary study design
Randomised controlled trial

Study setting(s)
Hospital

Study type(s)
Treatment

Participant information sheet
Not available in web format, please use the contact details to request a patient information sheet

Health condition(s) or problem(s) studied
Bothersome voiding lower urinary tract symptoms, or urinary retention, secondary to benign prostatic obstruction

Interventions
ThuVARP versus TURP in men with BPO.

The trial compares conventional TURP, the current gold standard, to the new laser technique of ThuVARP. All eligible men referred for consideration of BPO surgery will be identified by the consultant, dedicated research nurse or designated team member at clinics in each centre. The consultant/research nurse will introduce the study to the patients and if interest is expressed,

provide further details of the study by means of the Patient Information Sheet. All men who enter the study will complete baseline questionnaires, including measurement of urinary and sexual symptoms, a urinary bladder diary and a flow test. Men who consent will be randomised to either having a TURP or ThuVARP. All consenting men will complete the follow-up questionnaires and diaries at 6 weeks by post, and at 3 and 12 months in the clinic. At 12 months they will also have a review appointment with their urologist and research nurse to evaluate the results of surgery including a maximum flow rate (Qmax) and an international prostate symptom score (IPSS), and to identify any problems or the need for other treatment.

Intervention Type
Procedure/Surgery

Primary outcome measure
Clinical effectiveness of ThuVARP and TURP in improving patient reported lower urinary tract symptoms (LUTS) as measured by the IPSS patient reported questionnaire and the objective measure of Qmax, 12 months after surgery.

Secondary outcome measures
All patient reported outcomes (PROs) will be recorded at baseline, 6 weeks (by post), 3 months and 12 months.

1. What is the cost-effectiveness of ThuVARP as compared to TURP in terms of the two primary outcomes and quality-adjusted-life-years (QALYs)? Measured using EQ-5D-5L (preference based general quality of life measure)
2. What is the comparative impact of each treatment on patient-reported LUTS, erectile function, quality of life and general health at 6 weeks after randomisation/surgery, 3 months and 12 months? Measured using the ICIQ-MLUTS (for symptom bother), International Index of Erectile Function (IIEF), ICIQ-MLUTSsex (measures of erectile function), ICIQ-LUTSqol (condition specific quality of life score), EQ-5D-5L (preference based general quality of life measure) and ICIQ-Satisfaction (measures satisfaction with surgery outcomes) to assess the full impact of the intervention on patients and the NHS.
3. What is the comparative satisfaction of men with each type of surgery? Measured using ICIQ-Satisfaction (measures satisfaction with surgery outcomes) to assess the full impact of the intervention on patients and the NHS.
4. What is the comparative effectiveness of these operations in men who present with LUTS as opposed to urinary retention? Measured using the ICIQ-MLUTS (for symptom bother), International Index of Erectile Function (IIEF), ICIQ-MLUTSsex (measures of erectile function) and ICIQ-LUTSqol (condition specific quality of life score)?
5. What are mens experiences of both procedures, including those presenting with LUTS or urinary retention?

Added 08/12/2017: Additional secondary outcomes:
1. Surgical complications is measured using Clavien-Dindo classification to 12 months post surgery
2. Length of hospital stay is measured using medical notes
3. Blood transfusion rate is measured using medical notes to 12 months post surgery
3. Post-operative catheterisation time is measured using medical notes
4. Haemoglobin (blood loss during surgery) is measured using blood tests pre and post operatively

5. Serum sodium (absorption of irrigation fluid) is measured using blood tests pre and post operatively
6. Post-void residual urine is measured using urinary flow tests at 12 months post surgery

Overall study start date
01/01/2014

Completion date
31/12/2017

Eligibility

Key inclusion criteria
Adult men over the age of 18 suitable for TURP, either in urinary retention or with bothersome lower urinary tract symptoms (LUTS), secondary to BPO.

Participant type(s)
Patient

Age group
Adult

Lower age limit
18 Years

Sex
Male

Target number of participants
410

Total final enrolment
410

Key exclusion criteria
Patients with:
1. Neurogenic lower urinary tract dysfunction (LUTS)
2. Prostate cancer
3. Previous prostate or urethral surgery
Added 08/12/2017:
4. A PSA outside of the normal age-related range and who have not had prostate cancer excluded
5. Men who are unable to give informed consent or complete trial documentation

Date of first enrolment
05/06/2014

Date of final enrolment
31/12/2016

Locations

Countries of recruitment
England

United Kingdom

Study participating centre
Bristol Urological Institute
Bristol
United Kingdom
BS10 5NB

Sponsor information

Organisation
North Bristol NHS Trust (UK)

Sponsor details
Trust Headquarters
Beckspool Road
Frenchay
Bristol
England
United Kingdom
BS16 1JE

Sponsor type
Hospital/treatment centre

Website
http://www.nbt.nhs.uk/

ROR
https://ror.org/036x6gt55

Funder(s)

Funder type
Government

Funder Name

Health Technology Assessment Programme

Alternative Name(s)
NIHR Health Technology Assessment Programme, Health Technology Assessment (HTA), HTA

Funding Body Type
Government organisation

Funding Body Subtype
National government

Location
United Kingdom

Results and Publications

Publication and dissemination plan
Not provided at time of registration

Intention to publish date

Individual participant data (IPD) sharing plan

IPD sharing plan summary

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
Protocol article	protocol	17/04/2017		Yes	No
Results article	results	04/07/2020	06/07/2020	Yes	No
Results article	results	01/09/2020	10/09/2020	Yes	No
Other publications	cost-effectiveness analysis	01/11/2020	08/02/2021	Yes	No