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The OPEN Trial: Open Urethroplasty versus Endoscopic Urethrotomy: Clarifying the management of men with recurrent urethral stricture

Submission date
28/11/2012

Registration date
29/11/2012

Last Edited
05/05/2021

Recruitment status
No longer recruiting

Overall study status
Completed

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
About 60,000 younger men aged less than 65 years in the UK suffer from a narrowing of the urinary channel just beyond the bladder (bulbar urethral stricture). The stricture causes trouble passing urine which is embarrassing for men and often leads to urine infection requiring time off work and visits to their doctor. The standard initial treatment is stretching of the urethra with a telescope (endoscopic urethrotomy), and about 15,000 of these procedures are carried out in the United Kingdom (UK) National Health Service (NHS) each year at a cost of over £10 million. This doesn't usually cure the problem and men have to come back for repeated urethrotomies, typically every two years, resulting in a continued burden for patients, ongoing costs for the NHS, and damage to healthy parts of the urethra. Recently a new operation called open urethroplasty has been developed whereby the urethra is surgically reconstructed through an incision in the skin between the legs. Open urethroplasty seems to have a much higher chance of curing the problem, preventing further symptoms and the need for regular stretches. It does however require more surgical expertise, and men have to have a urinary catheter in place for 2 weeks rather than the 2 days with urethrotomy. At present we don't know for sure which procedure is best suited to stopping recurrence of the stricture and improving men's symptoms, and which provides best value for money to the NHS. Because of this uncertainty, doctors find it difficult to recommend one treatment or another and the men themselves are unable to make an informed choice between the treatments. To resolve this dilemma we intend to carry out a randomised clinical study in a group of men with recurrent urethral strictures to find out which procedure is most effective, and use the results to predict the health benefits for these men and the financial implications for the NHS, over 10 years. Our research questions are: Do open urethroplasty and endoscopic urethrotomy for treatment of men with urethral stricture differ regarding effective symptom relief? Does open urethroplasty provide better value in terms of cost and health benefit than endoscopic urethrotomy for both patients and the NHS?

Who can participate?
We plan to recruit at least 500 men who have a recurrent bulbar urethral stricture. They must be

aged 16 or over, have had at least one previous intervention for stricture and be prepared and able to have either an open urethroplasty or an optical urethotomy.

What does the study involve?
The study will be carried out in up to 50 UK NHS hospitals. Participants will be randomly allocated to either an open urethroplasty or an optical urethotomy. Care received by participants will follow routine clinical practice in each hospital. We will monitor all the participants for 2 years following their treatment, measuring change in symptoms, general well-being, urinary flow rate and rate of recurrence of the stricture. We will record any problems men encounter linked to the operation such as infections and needing time off work, and collect information on the costs. We will better understand patient views by interviewing up to 20 potential participants in the early part of the study to find out how they weigh up the pros and cons of each treatment and decide which is best for them. This will help identify factors that influence men in making a choice between the treatments.

What are the possible benefits and risks of participating?
Those randomised to urethroplasty will potentially benefit from more effective treatment and both groups will have their disease more closely monitored than is usual. The study results will help shape presentation of treatment options to future men with stricture. Potential participants will need to understand the uncertainty as to which treatment is best and accept allocation to one or other treatment by computer.

Where is the study run from?
The study is managed by the Newcastle Clinical Trials Unit based at Newcastle University, Newcastle upon Tyne, UK.

When is the study starting and how long is it expected to run for?
The study started in November 2012 and is planned to end in February 2017. Participant recruitment is scheduled to start in February 2013 and end in January 2015.

Who is funding the study?
National Institute for Health Research (NIHR) Health Technology Assessment (HTA) Programme and the Clinical Evaluation and Trials Board.

Who is the main contact?
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Study website
www.opentrial.co.uk

Contact information

Type(s)
Scientific

Contact name
Dr Rachel Stephenson

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Additional identifiers

EudraCT/CTIS number

IRAS number

ClinicalTrials.gov number

Secondary identifying numbers
HTA 10/57/23, 13507

Study information

Scientific Title
Clarifying the management of men with recurrent urethral stricture: A pragmatic multicentre randomised superiority trial of open urethroplasty versus endoscopic urethrotomy

Acronym
OPEN

Study objectives
Every year over 4,000 men in the United Kingdom require surgery for recurrent bulbar urethral stricture, a narrowing of the urinary channel just beyond the bladder. The stricture causes trouble passing urine which is embarrassing for men and often leads to urine infection. The standard treatment is stretching of the urethra with a telescope - endoscopic urethrotomy, but this doesn't usually cure the problem and men have to come back for repeated surgery, typically every two years. Recently a new operation called open urethroplasty has been developed whereby the urethra is surgically reconstructed through an incision in the skin beneath the scrotum. Open urethroplasty seems to have a much higher chance of curing the problem, preventing further symptoms and the need for regular stretches, but is more invasive. At present we don't know for sure which procedure is best for symptom relief and has the lowest rate of recurrence. Urologists treating men with urethral stricture find it difficult to recommend one treatment or another and the men themselves are unable to make an informed treatment choice. We therefore intend to carry out a randomised clinical trial in a group of men with recurrent bulbar urethral strictures to find out which procedure is most effective, and use the results to predict the health benefits for these men and the financial implications for the NHS, over 10 years.

Ethics approval required
Old ethics approval format

Ethics approval(s)
Newcastle and North Tyneside 1, first MREC approval date 22/10/2012, ref: 12/NE/0343

Study design
Pragmatic multicentre randomised superiority 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 contact Rachel Stephenson [Rachel.Stephenson@newcastle.ac.uk] to request a patient information sheet

Health condition(s) or problem(s) studied
Recurrent urethral stricture

Interventions
We need to randomise at least 500 men recruited from NHS hospitals to undergo either of the two options of endoscopic urethrotomy and open urethroplasty and then follow their progress over 2 years. During this period we will repeatedly measure urinary symptoms, quality of life, adverse effects including need for further surgery, and costs. The difference in improvement of urinary symptoms over the 24 months will be the primary outcome for the trial.

Intervention Type
Procedure/Surgery

Primary outcome measure
ICIQ-Male Short Form questionnaire repeated measurement over 24 months following intervention

Secondary outcome measures
No secondary outcome measures

Overall study start date
01/11/2012

Completion date
01/02/2017

Eligibility

Key inclusion criteria
1. Adult men aged 16 years or older
2. Stricture located predominantly in bulbar urethra
3. Undergone at least one previous intervention (urethrotomy, dilatation, or urethroplasty) for bulbar stricture
4. Clinician and patient agreement that intervention is required
5. Suitable for general or regional anaesthesia of up to 3 hours duration
6. Willingness to have 2 week period of catheterisation
7. Provided written informed consent for participation in the study prior to any study specific procedures

Participant type(s)
Patient

Age group
Adult

Sex
Male

Target number of participants
Planned Sample Size: 500; UK Sample Size: 500

Total final enrolment
222

Key exclusion criteria
1. Age less than 16 years
2. Stricture extending into membranous urethra or predominantly sited in penile urethra
3. Presence of perineal sepsis and/or fistula
4. No previous intervention for bulbar stricture
5. High anaesthetic risk or inability to adhere to protocol due to comorbidity
6. Inability or unwillingness to provide informed consent to randomisation
7. Previous participation in this study

Date of first enrolment
01/02/2013

Date of final enrolment
31/01/2015

Locations

Countries of recruitment
England

United Kingdom

Study participating centre
Newcastle Clinical Trials Unit
Newcastle upon Tyne
United Kingdom
NE2 4HH

Sponsor information

Organisation
Newcastle upon Tyne Hospitals NHS Foundation Trust (UK)

Sponsor details
Joint Research Office
Leazes Wing
Queen Victoria Road
Newcastle upon Tyne
England
United Kingdom
NE1 4LP

Sponsor type
Hospital/treatment centre

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

ROR
https://ror.org/05p40t847

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
01/08/2018

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	30/12/2015		Yes	No
Results article	results	27/03/2017		Yes	No
Results article	results	01/11/2020	25/11/2020	Yes	No
Other publications	cost effectiveness analysis	03/05/2021	05/05/2021	Yes	No