OPEN
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Participant Information Sheet

Study comparing open and endoscopic surgery for recurrent urethral stricture in men

Invitation

You are invited to take part in a research study. It's called the OPEN trial. Before you decide we would like you to understand why the research is being done and what it would involve for you. One of our team will go through this information sheet with you and answer any questions you have. Talk to others about the study if you wish and please ask us if there is anything that is not clear.

Part 1 tells you the purpose of this study and what will happen to you if you take part.

Part 2 gives you more detailed information about the conduct of the study.

Part 1

What is the purpose of this study?
The OPEN trial is about finding the best way to treat recurrent urethral strictures in men.

The urethra is the tube that carries urine from the bladder to the tip of the penis. People sometimes call it the 'water pipe'. One in 300 men are affected by a condition called urethral stricture where part of the urethra gets a scar in it and narrows down. Strictures are usually caused by a urine infection or an injury to the urethra and the most common symptom is trouble passing urine. The other problem with urethral strictures is their tendency to come back after treatment.

There is more than one treatment for urethral stricture. The standard way is a keyhole operation to cut through the scar in the urethra called **endoscopic urethrotomy**. The newer alternative is to repair the urethra through a cut in the skin between the legs. This is called **urethroplasty**.

Endoscopic urethrotomy is performed by putting a thin video camera (endoscope) inside the urethra. There are no cuts in the skin. A knife on the end of the camera is used to make a cut through the stricture. Doing this returns the urethra to its normal width.

Urethroplasty is a different kind of operation. A cut is made in the skin between the legs to expose the urethra from the outside. If the stricture is short the surgeon can cut it out and join the urethra back together with stitches. When the stricture is too long to pull the healthy ends together, a small piece of the patient's inner mouth lining is used to rebuild the narrow section.

Endoscopic urethrotomy and urethroplasty are performed under anaesthetic by a surgeon specialising in the waterworks (a urologist). Both operations involve having a catheter tube in afterwards while the urethra heals. Men who have an endoscopic urethrotomy need to have a catheter in for three days on average. Men who have a urethroplasty need to have a catheter in for about two weeks.

Your urologist will go through both operations in detail.

As a rule it is technically simpler to cut through the scar in the urethra than to repair it. Endoscopic urethrotomy takes about half an hour and most men get home from hospital within a day or two. The downside is that the problem will usually come back – most men who have this operation will see their stricture return within two years. Urethroplasty is a bit more complicated to perform. It takes two to three hours and the average hospital stay is two days. There's also a cut in the skin. It is thought that the benefit men get from urethroplasty may last longer and most men who have this treatment don't need another operation on their urethra in the next five years. Each option has its pros and cons and it is uncertain which option is better overall.

At the moment men have to choose the operation that feels right for them based on the limited information that doctors can provide as there are no studies directly comparing the results of the two options. We have launched this study so that in future we can give the best advice to men with urethral strictures. We want to know which men are better off having an endoscopic urethrotomy repeated as needed, and which men are better off with a urethroplasty.

When doctors don't know which way of treating patients is best we compare different treatments directly to find out. We put patients into groups and give each group one of the different treatments. To try to make sure the groups are the same to start with, each patient is put into a group by chance. This is called randomisation.

To compare endoscopic urethrotomy and urethroplasty we need 210 men who have already decided to have an operation for their recurrent urethral stricture to agree to have the type of operation chosen at random. Half of the group (105 men) will have an endoscopic urethrotomy and the other half will have a urethroplasty. After the operation we will ask all 210 men to fill out a series of questionnaires about their waterworks and general health to see which one worked better.

Why have I been invited?
Your urethral stricture has come back and you have decided to have it treated. Your urethral stricture can be treated by either endoscopic urethrotomy or urethroplasty.

Do I have to take part?
No. It's up to you to decide. We will describe the study and go through this information sheet with you. If you agree to take part we will ask you to sign a consent form. You can withdraw from this study at any time without giving a reason. This would not affect the standard of care you receive.

What will happen to me if I take part?
If you decide to take part your urethral stricture operation will be decided at random by a computer. The computer acts like flipping a coin. The only thing it can do is to select the operation you will have:

a) Cut the scar in the water pipe (endoscopic urethrotomy).

b) Repair the scar in the water pipe (urethroplasty).

It is important to understand that to take part in the OPEN trial neither you nor your urologist can decide which of the two operations you will have. The computer will select your operation at random and you will go on to have that operation performed in the normal way by a urologist. To take part you must be prepared to have either operation.

What will I have to do?
Apart from randomisation we have designed this trial so that your health care is much the same as if you were not in the trial. The extra things you will need to do are complete a series of short health questionnaires, cost questionnaires, and do a urine flow rate test three times.

The health questionnaires tell us how troublesome your waterworks symptoms are, how you feel about your health, and about any further surgeries you have had for treatment of your stricture. You will be asked to fill them out once after consenting, once before your operation; once just afterwards, and 3, 6, 9, 12, and 24 months after your surgery, 18 and 24 months after you enter the OPEN study, and at the end of the study in December 2017 (eleven times in total).

The cost questionnaires tell us the costs involved in your treatment by understanding how many times you use NHS services for treatment of your recurrent urethral stricture, and how much it has cost you to attend for this treatment (for example, travel costs). You will be asked to fill them out 6 and 12 months after your surgery, and 18 and 24 months after you enter the OPEN study (four times in total).

You won't need to worry about remembering to fill the questionnaires in on time – a member of the study team will contact you when they need to be completed. You'll have the option of completing the questionnaires on paper or online on our secure website.

The flow rate test tells us how quickly you pass urine. When you come for your routine hospital follow-up appointment we will ask you to pass urine in private into a toilet fitted with a water flow sensor. You will need to do this before the operation, and three months and two years afterwards.

Is there anything else I might be asked to do?
A small number of men who agree to take part in the OPEN trial and an equal number who don't agree to take part will be invited to discuss their feelings about this trial and the choice between urethrotomy and urethroplasty in an interview. This is for a separate interview study running alongside the main OPEN trial. It's optional and there's a separate box on the consent form you can initial to register your interest.

Expenses and payments
We understand that being in research study takes time and effort. If you decide to take part you will be offered a £25 gift voucher at the start of the study, another £25 gift voucher after completing your 24 month after study entry questionnaire, and another £25

gift voucher , at the end of your involvement in the study in December 2017. These vouchers are to say thank you for your time and contribution. We will also reimburse extra expenses you incur as a result of taking part; for example, the cost of travel to the hospital when you wouldn't normally have needed to attend, up to £25 per visit.

What other treatments are there for urethral strictures?
There are no good alternatives to endoscopic urethrotomy and urethroplasty. Sometimes men who undergo endoscopic urethrotomy are taught how to stretch the urethra themselves by passing a catheter tube in to it about once a week at home. This is called intermittent self-dilatation (ISD). If you want to do ISD you can still take part in the OPEN trial.

What are the benefits of taking part?
During the trial you will be under closer follow-up than normal and will learn more about your problem from the information we will give you. You will also be helping to improve the treatment of men with urethral strictures in the future.

What are the disadvantages or risks of taking part?
The disadvantage of randomisation is that you will not be able to choose between the two types of operation you can have for your urethral stricture. You will have to be prepared to have either operation. Before participating you should also think about whether it will affect any health insurance you have and seek advice if necessary.

What are the side effects of endoscopic urethrotomy and urethroplasty?
Endoscopic urethrotomy and urethroplasty carry risks. These risks are not increased by taking part in this study because whichever operation you have will be performed in the same way as normal. Most men have these operations and don't have any problems, but the main things that can go wrong are described below.

Endoscopic urethrotomy
Common risks are:

- Temporary mild bleeding or discomfort on passing urine.
- Water infection that requires antibiotics.

Less common risks are:

- Bleeding that requires emergency surgery.
- Serious infection that spreads to the bloodstream.

Rare complications are:

- Leaking urine from the cut in the water pipe and the catheter has to stay in longer while it heals.
- Difficulty getting an erection that lasts up to a year.

Urethroplasty
Common risks are:

- Temporary discomfort in the mouth if a piece of mouth lining is used.
- Temporary discomfort in the wound between the legs.
- Infection in the skin wound between the legs that requires antibiotics.
- Water infection that requires antibiotics.
- Passing urine normally then dribbling a few drops on your underwear moments later (called post-micturition dribble).

Less common risks are:

- Having to leave the catheter in longer because the urethra is slow to heal.
- Severe pain or scarring in the mouth if a piece of mouth lining is used.
- Serious infection that spreads to the bloodstream.

Rare complications are:

- Severe wound infection that spreads to the layers beneath the skin.
- The join in the urethra doesn't heal properly and urine leaks from a hole in the skin wound. Another operation is required to close the hole.
- Difficulty getting an erection that lasts up to a year.

Both operations carry a risk of the stricture coming back. We already know that the risk is higher if you have an endoscopic urethrotomy. If this happens you will not be expected to have another operation at random. Your urologist will talk to you about the options and you can make a free choice between one treatment and another.

What happens when the research study stops?
Your active participation in the OPEN trial will end once you've completed the last questionnaire two years after your operation. If you agree to take part we will follow your progress and health status through your NHS records for a total of ten years from the date you have your operation and through the NHS Health and Social Care Information Centre and other central NHS bodies after that, but you won't need to do anything while that happens. We may contact you after you have left the trial to find out how you are getting on. There is a separate box on the consent form you will need to initial to agree to this.

Will my taking part in the study be kept confidential?
Yes. We will follow ethical and legal practice and all information about you will be handled in confidence. The details are included in Part 2.

What if there is a problem?
Any complaint about the way you have been dealt with during the study or any possible harm you might suffer will be addressed. The detailed information on this is given in Part 2.

This completes Part 1 of the information sheet. If the information in Part 1 has interested you and you are thinking about taking part, please read the additional information in **Part 2** before making a decision.

Part 2

What will happen if I don't want to carry on with the study?
You can withdraw from this study at any time without giving a reason. If you decide to withdraw from the study we will need to use the information you have already given us for our research.

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 first who will do their best to answer your questions (their contact number is 0191 222 8979). If you remain unhappy and wish to complain formally, you can do this through the National Health Service complaints procedure. Details can be obtained from the Patient Advice and Liaison Service (PALS http://www.nhs.uk/Service-Search/Patient%20advice%20and%20liaison%20services%20(PALS)/LocationSearch/363) at your local hospital. Their contact number is [LOCAL PALS CONTACT].

If something does go wrong and you are harmed during the research and this is due to someone's negligence then you may have grounds for legal action for compensation against the NHS Trust that treated you or the trial's sponsor organisation The Newcastle upon Tyne Hospitals NHS Foundation Trust, but you may have to pay your legal costs. The normal NHS complaints mechanisms will always be available to you.

Will my taking part in the study be kept confidential?
Yes. If you agree to take part in this study, the records obtained while you are in the study as well as related health records will remain strictly confidential. Your information will be held securely on paper and electronically at your treating hospital and at the two trial centres (Newcastle Clinical Trials Unit and the Centre for Healthcare and Randomised Trials in Aberdeen) who are managing this research. Your name will not be passed to anyone who is not involved in the trial. You will be allocated a trial number, which will be used as a code to identify you on trial forms. Information about you which leaves the trial offices will have your name and address removed. Your contact details will be kept securely so we can stay in touch regarding your progress.

Your records will be available to people authorised to work on the trial but may also need to be made available to people authorised by The Newcastle upon Tyne Hospitals NHS Foundation Trust, which is the Sponsor organisation responsible for ensuring that the study is carried out correctly. By signing the study consent form you agree to this access for the current study and any further research that may be conducted in relation to it, even if you withdraw from the current study.

In line with the regulations, at the end of the study your data will be securely stored for 10 years. Arrangements for confidential destruction will then be made.

Will my GP be informed of my involvement?
With your permission, your GP and other doctors who are treating you will be informed that you are taking part in the OPEN trial.

What will happen to the results of the research study?
The results will be presented at research meetings, and published on the National Institute for Health Research Health Technology Assessment programme website and in scientific journals. We will also make the results widely available to the public. You will not be identified in any report or publication.

Who is organising and funding the research?
This study is being organised by the Newcastle University's Clinical Trials Unit and the Centre for Healthcare and Randomised Trials at Aberdeen University. It is sponsored within the NHS by The Newcastle upon Tyne Hospitals NHS Foundation Trust and funded by the National Institute for Health Research Health Technology Assessment programme.

Who has approved the study?
All research in the NHS is looked at by an independent group of people called a Research Ethics Committee to protect your interests. This study has been reviewed and given favourable opinion by the Newcastle and North Tyneside North East Research Ethics Committee.

What do I do now?
You will be contacted by a member of the research team. Please let them know whether you would like to take part.

Further information and contact details
If you have any further questions concerning this study please contact:

Local Principal Investigator	**Local Research Nurse**
Address	Address
Phone:	Phone:
Fax:	Fax:
Email:	Email:

Thank you for thinking about taking part in our research.

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Consent Form for Randomisation

Patient Identification Number | | | | | |

Title of Project: OPEN: Clarifying the management of men with recurrent urethral stricture: a pragmatic multicentre randomised superiority trial of open urethroplasty versus endoscopic urethrotomy.

Name of Researcher: Professor Robert Pickard

Name of Local Principal Investigator ……

By initialing each box and signing this form:

1. I confirm that I have read and understand the information sheet dated 17th February 2015 (version 1. 5) for the above study. I have had the opportunity to consider the information, ask questions and have had these answered satisfactorily. ☐
2. I understand that my participation is voluntary and that I am free to withdraw at any time without giving any reason, without my medical care or legal rights being affected. ☐
3. I understand that sections of my medical notes and data collected during the study, may be looked at by individuals from regulatory authorities, from the NHS Boards or Trusts, or from Newcastle University or the University of Aberdeen, where it is relevant to my taking part in this research. I give permission for these individuals to have access to them. ☐
4. I understand that the research team will follow my progress regarding urethral stricture disease after the end of the study through my local and centrally stored NHS records ☐
5. I agree to my GP being informed of my participation in the study. ☐
6. I agree to take part in the above OPEN study. ☐
7. I am willing to be contacted about the separate interview study. ☐
8. I am willing to be contacted in future for long term follow-up. ☐

Name of Patient	Date	Signature
Name of Person receiving consent	Date	Signature

When completed: 1 original for site file; 1 copy for patient; 1 copy for hospital notes; 1 copy faxed to trial office.