Participant Information Sheet

Study to find out what men think about the side effects of urethral stricture operations

Invitation

You were recently asked to take part in a research study called the OPEN trial. This is a further invitation to take part in a separate interview study running alongside the OPEN Trial. It is entirely optional and you can agree to an interview even if you did not want to enter into the OPEN trial.

Before you decide we would like you to understand why this research is being done and what it would involve for you. One of our team will go through the 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.

The first part of this information sheet tells you the purpose of the study and what will happen. If you are interested, you can read the more detailed information provided in the second section.

WHAT IS THE STUDY ALL ABOUT?

The purpose of the study is to find out how men feel about the common and rare short term side effects of different urethral stricture treatments and how strongly they would want to avoid those side effects and discomforts. We are looking to speak to as many men as possible to get their point-of-view.

Why have I been invited?

You have been invited because you have a urethral stricture and were invited to take part in the OPEN trial. Even if you did not take part in the trial we would still like to hear from you. We would like to hear your views on the side effects of the different urethral stricture treatments.

Do I have to take part in an interview?

No, it's entirely up to you. Your decision will not affect the standard of your care and, if you change your mind, you can withdraw from the interview at any time. If you withdraw from the study during or after the interview, we will ask you if we can use any information collected up to your withdrawal for our research. If you do not want us to use your information it will not be used and will be erased from our records.

OK, so what happens next?

If you agree to be interviewed, a researcher from Newcastle University will contact you first by phone. They will answer any questions you have and arrange a time and place for the interview. The interview will be done in person at your local hospital or in your own home if you wish.

What happens in the interview?
The interview will take around forty-five minutes to one hour. You will be shown some health profiles on a number of colour coded cards and each of the profiles will describe a health state with some common or rare side effects following a particular urethral stricture treatment. The cards will then be placed on a board where you will be asked to compare the health profiles. You will also be asked some questions about yourself at the interview by filling in a short questionnaire.

How will the interview be used?
The information obtained in the interview will be used by the researchers to evaluate the negative feelings men have towards those short term side effects, which will then be used to evaluate the treatments and inform treatment decisions. Your name and any personal details will be removed from the written version so that everything you have said is anonymous. We hope to publish the results of the study in scientific journals, which may include anonymised quotations.

Expenses and payments
We will try to arrange the interview at the hospital where you normally go for your treatment and try to arrange it so that it coincides with your routine hospital outpatient appointment. We will reimburse any extra expenses you incur as a result of taking part, up to a maximum of £25; for example, the cost of travel to the hospital when you wouldn't normally have needed to attend.

What are the benefits of taking part?
You will be helping us improve the treatment of men with urethral strictures and make more informed decisions on the treatment offered to patients. There will be no direct benefits for you.

What are the disadvantages of taking part?
The interview will take between forty-five minutes and an hour of your time.

What happens after the interview?
You will only be asked to do one interview and your health care will be completely unaffected. If you are taking part in the main OPEN trial you will be followed up in the way described in the other information sheet you were given for that trial.

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 the next part.

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 the next part.

This completes the overview of the interview study, if you are interested in taking part please read the additional information below before making a decision.

FURTHER DETAILS OF THE STUDY

What will happen if I don't want to carry on with the interview study?
You can withdraw from this study at any time without giving a reason. If you withdraw from the study during or after the interview we will ask you if we can use any information collected up to your withdrawal for our research. If you do not want us to use your information it will not be used and will be erased from our records.

What if there is a problem?
If you have a concern about any aspect of this study, you should ask to speak to the lead researcher for the interview study, Professor Luke Vale, first who will do his best to answer your questions (his contact number is 0191 208 5590). 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.pals.nhs.uk/) at your local hospital. Their contact number is [LOCAL PALS CONTACT].

Because this interview study does not involve any tests or treatment it is highly unlikely that you will be harmed during the research. If something does go wrong 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. 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 this study as well as related health records will remain strictly confidential. There will be no audio-recording at the interview. A questionnaire will be filled in during the interview. The questionnaires will be held at Newcastle University. Questionnaires will be labelled with a trial number (not with your name) to hide your identity and will be securely stored by the research team. The anonymised questionnaires will be securely stored for up to a maximum of 15 years afterwards, and then they will be destroyed. Only the researchers and those employed on the study will have access to the questionnaires.

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 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 consent form you agree to this access for the current study and any further research that may be conducted in relation to it.

What will happen to the results of the research study?
The study 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?
The OPEN trial interview study is being led by Dr Jing Shen who is a health economist based at Newcastle University's Institute of Health & Society. 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 1 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:

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Or

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Thank you for thinking about taking part in our research.

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Consent Form for Patient Interview

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

Study to find out what men think about the side effects of urethral stricture operations

Participant Study Number ☐☐☐☐-☐☐☐

Name of Chief Investigator Professor Robert Pickard

Name of Lead Researcher, Interview Study Dr Jing Shen

Name of Local Principal Investigator ……..

By initialling each box and signing this form:

1. I confirm that I have read and understand the information sheet dated 11 November 2014 (version 1.3) 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 relevant sections of my medical notes and data collected during the study, may be looked at by individuals from regulatory authorities, from Newcastle University, or from the NHS Boards or Trusts, where it is relevant to my taking part in this research. I give permission for these individuals to access my records. ☐

4. I understand that I will not be personally named in any report and that anything I say will be treated in confidence (unless something I say indicates that either myself or someone else is at risk of harm and this would be discussed with me prior to telling anyone else). ☐

5. I agree to take part in the above interview study. ☐

Name of Patient	Date	Signature
Name of Person taking consent	Date	Signature

When completed: 1 original for researcher; 1 copy for patient; 1 copy for hospital notes.