Male synthetic sling versus Artificial urinary Sphincter Trial for men with urodynamic stress incontinence after prostate surgery: Evaluation by Randomised controlled trial

MASTER TRIAL

PATIENT INFORMATION LEAFLET

The purpose of the MASTER research study is to compare two different types of surgery for men with urine leakage (urinary incontinence) after prostate surgery, in order to identify the most effective operation. This will be done by dividing men who suffer from urinary incontinence between two different types of surgery that are used to treat this problem. The improvement in urinary incontinence will be used to compare the success of the surgeries. The results from this study will show which operation is the most effective operation in treating urinary incontinence and will help men who suffer from the problem in the future.

Please take time to read this information leaflet and discuss it with your family, friends or GP if you wish.

Do not hesitate to contact us if there is anything you do not understand or if you would like more information.

master@abdn.ac.uk

or

01224 438096

v4.2 21 March 2016

1. Description of Study

There are two main types of operation used to treat urine leakage (incontinence) resulting from prostate surgery. There is not enough evidence from previous research to let us know which operation should be used. This study is comparing these two operations, which use different devices. The Surgical Information Sheet, which you have also received, gives the details of the differences between the two operations, the male sling and the artificial urinary sphincter (AUS). The AUS has been used for 40 years, but the male sling is newer. Because of this, NICE, the National Institute for Health and Clinical Excellence, does not recommend the male sling unless it is in a research study. This is why we are doing this research and the male sling will not normally be available outside this study.

2. Why have I been invited to take part?

You are being invited to take part in the MASTER study because you will be having an operation for your urine leakage. Before you decide, it is important for you to understand why the research is being done and what it will involve. Please take time to read the following information carefully.

3. Background

One in fifty men will need an operation for urine leakage after prostate surgery. Both types of surgery that you might undergo in this study are in use in the NHS. You will find more information about these in the Surgical Information Sheet, and your urologist will also discuss these with you. We would like to be able to compare the results of these two different operations, particularly in the long term. Your participation in the study will help us do so.

You will not have to undergo any tests or procedures that are not part of routine care for this type of surgery.

There may be no direct benefit to you if you do take part, but you will be helping with research to enable doctors to assess which operation is best and most effective for future patients.

4. What is the purpose of the study?

The aim of the study is to find out which of the operations gives the best results and is most effective. Therefore, when the study is finished, doctors in the future will be able to choose the surgery that has the best results with the fewest problems. This may include better health and quality of life for men, less need for further operations and better use of NHS facilities.

5. Do I have to take part?

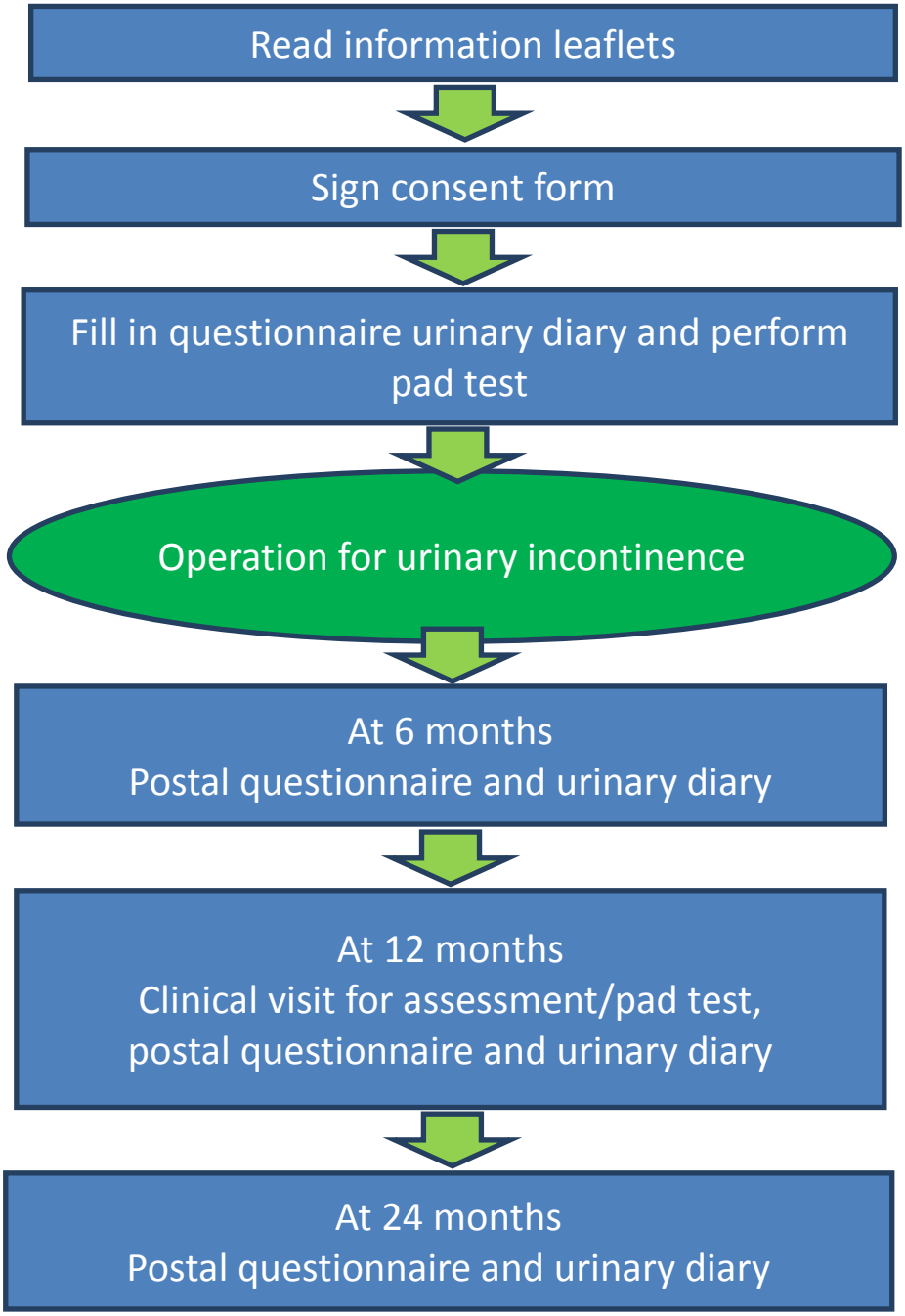
No, it is up to you whether you decide to take part. If you do take part you would be free to withdraw at any time without giving any reason. This will not affect your current or future medical treatment. Before you decide, your urologist or the MASTER research nurses will provide you with more information and will be happy to discuss any questions you may have. If you agree to take part, you will be asked to sign a consent form for this research study. Your urologist will make you aware of all

relevant issues surrounding the surgery itself, and you will sign a separate NHS information and consent form for your operation.

6. What will happen if I take part?

As described in the Surgical Information Sheet, there are two different types of operation that you could have. If your urologist thinks that either of the operations would be equally suitable for you, with your agreement you will be put into one group by chance (randomly). All of the men in that group will be given the same operation. You will not be told which operation you are going to have before surgery. After the operation we will tell you whether you have had the Male Sling or the AUS.

The following diagram shows you what you will be asked to do:



Each questionnaire will take about 10-20 minutes of your time to complete. Your answers will help us measure how things have changed after the operation.

Although we would like you to complete the questionnaires fully, you are not obliged to answer every question if you don't want to.

You will also be asked to perform a urinary pad test which measures the amount of urine you lose in 24 hours. This will be done by wearing absorbent pads for 24 hours, and then these wet pads are taken with you when you attend the hospital to be weighed. We will also ask you to fill in a 3 day urinary diary. Together this gives the study team measurements of your urine leakage.

7. Further Research

A further part of the MASTER study will involve members of the study team approaching some of the men being studied to invite them to take part in additional research to talk about their expectations and point of view on urine leakage after prostate surgery. This will involve having a short interview which will either be in person or over the telephone. We may contact you in the future about this part of the study and will provide you with a participant information sheet and an additional consent form. It is up to you if you would like to take part in this additional part of the study and this will not affect any other part of the study.

With your permission, we would like to contact you again after the two year follow up to a) check on your long term health, for example by sending you other questionnaires to add information to what we already know about you, or by checking your medical NHS records; and b) to ask you to take part in other relevant studies. However, you will not have to reply to any questionnaires or take part in other studies unless you want to at that time.

8. Will the information I provide be kept confidential?

Yes, all information collected for the study at any time will be stored using a Study Identity Number for confidentiality and will be kept secure using passwords. This includes the questionnaires that may be sent to you in the longer term as mentioned above. The information will only be available to the research team and the NHS or University bodies responsible for maintaining research standards. Your own doctor (GP) will be informed of your participation in the study.

In order to increase the usefulness of the whole study, we plan to confidentially link your answers with electronic data from your medical NHS records related to your health after your surgery. We will ask you for specific consent to this, again this information will be kept secure and confidential.

Other researchers may wish to access data from this study in the future: this will not include names, addresses or dates of birth, and it will not be possible to identify participants in any way. If other researchers request to access the data, the consultant leading the study will ensure that the other researchers comply with legal, data protection and ethical guidelines.

9. How will the information I provide be used?

We hope that around 700 men will take part in this study during the next three years in centres across the UK. Urologists will be informed of the recommendations from the study, so that in future all men can receive the best and most effective operations. The results of the study will be published in scientific journals and a short

version will also be available to those men who took part in the study if they wish. Men will not be identifiable in any of the study reports.

10. What will happen if I don't want to carry on with the study?

You can withdraw from the study at any time, but you will continue to receive your standard NHS care after surgery, such as attending appointments with your consultant.

11. What if there is a problem?

Both of the operations are already being used in the NHS for incontinence surgery. Your participation in the study is therefore only to help us compare these procedures with each other and should not involve any additional risk to you.

Taking part in this study does not affect your normal legal rights. Whether or not you do take part, you will retain the same legal rights as any other patient in the NHS (which includes professional indemnity insurance for negligence). If you wish to complain about your health care or any aspects of this study, the normal NHS mechanisms will be available to you. Although we do not expect participation to affect private medical insurance, please check with your insurers before agreeing to take part in the study.

If you have a concern about any aspect of the study, you should ask to speak with the research team who will do their best to answer your questions (phone 01224 438096). 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.

If you became unable or unwilling to continue in MASTER, we would withdraw you from the study. We would retain, confidentially and with your consent, the relevant information that we had already collected about you, for the purposes of the study only.

12. Who is doing this study?

This study is being funded by the NHS National Institute for Health Research Evaluation, Trials and Studies Coordinating Centre, Health Technology Assessment programme (NETSCC HTA). The research is being carried out by a group of experienced doctors and researchers from the Bristol Urological Institute and the Health Services Research Unit at the University of Aberdeen, in collaboration with the British Association of Urological Surgeons.

13. Who has approved this study?

Your local hospital, your urology consultant and Frenchay Research Ethics Committee in Bristol have given approval for this study to be carried out. An independent Trial Steering Committee and a Data Monitoring Committee monitor safety and ensure that the study is conducted in accordance with good research practice.

14. How do I get in touch with the research team if I want any further information about the study?

If you have any questions about the study, or any aspect of your treatment or health, please speak to your MASTER research nurse or your own urology consultant or GP. Alternatively you can contact the MASTER Study Office (details over).

You can contact the study team who are organising the research:

Trial Manager
MASTER STUDY OFFICE
Centre for Healthcare Randomised Trials (CHaRT)
Health Services Research Unit
University of Aberdeen
Health Sciences Building
Foresterhill Aberdeen AB25 2ZD
Tel. 01224 438096

or the Chief Investigator
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BS10 5NB

Or you can email us at:

master@abdn.ac.uk

Thank you for reading this leaflet & considering taking part in MASTER.

Funded by the National Institute for Health Research Health Technology Assessment (NIHR HTA) Programme 11/106/01