Patient Information Sheet

CONCUR – CONtractility: **C**uff versus **UR**odynamics testing in males with voiding lower urinary tract symptoms

Invitation

You have been invited to take part in a research study being run by the Urology department at the Freeman Hospital, in conjunction with Newcastle University. This leaflet is designed to give you information about why the study is happening and what would be involved if you decide to participate. Please read the information carefully, and discuss it with a relative or friend if you wish. If there is anything you do not understand, or if you have any questions, contact details are provided at the end of this leaflet.

Study Summary

A number of men will experience bothersome urinary symptoms within their lifetime, and this is more common as men get older. There are a number of conditions which can cause these symptoms, and general practitioners may refer men with these problems to their local hospital for further assessment and treatment. Men who describe a poor flow of urine, the need to pass urine more frequently, or feel that their bladder is not completely emptying, may have enlargement of the prostate gland, but these symptoms can also be caused when the bladder muscle is not able to contract (squeeze) as well as it previously has to empty the bladder. This condition is known as underactive bladder (UAB).

It is important to be able to distinguish between prostate enlargement and underactive bladder as a cause for these symptoms, to prevent side effects from unnecessary medications or operations. Currently to do this, men would need to undergo a bladder pressure test (urodynamics). This involves inserting a catheter via the penis into the bladder, through which the bladder is filled with fluid and pressure is measured. A separate second small tube is inserted into the rectum to measure the pressure in your abdomen. The pressure changes are observed as the bladder is filled, and then as you pass urine around the catheter. The disadvantage of this standard approach is the need for the two tubes internally, and the small risk of urine infection or blood in the urine as a result of the bladder catheter.

A second technique for measuring the pressure within the bladder is the use of a small inflatable cuff (similar to those used to measure blood pressure, on a smaller scale) which is placed around the penis (penile cuff test). The bladder pressure can then be determined by inflating the cuff and interrupting the flow of urine. The bladder can be filled naturally before the test, which means a bladder catheter tube is not required. This study is designed to find out ways we can make the penile cuff test even more accurate, and compare this to results obtained from the bladder pressure test.

Why have you been chosen?

You have been referred by your urologist for a bladder pressure test to investigate your urinary symptoms. All men referred for this test have been invited to take part in this study.

Do you have to take part?

No, it is your decision whether you take part or not. If you choose not to take part, you will be sent an appointment for the standard bladder pressure test as requested by your doctor. If you do decide to participate in this study, you are free to withdraw at any point, which would not affect the standard of the care you receive from the department.

What will you have to do?

If you agree to consider take part you will be contacted by one of our research team to discuss any question you may have, and you will be asked some questions to assess whether you meet the criteria for the study. An appointment will be scheduled within the department. Details of this will be sent out by post, as well as a chart for you to complete ahead of the appointment measuring your urine frequency and volumes across 4 days. You may have already completed one of these before with your GP or urology consultant.

A member of the research team will meet you when you attend for your appointment, and go through a patient consent form which you will be required to sign before the investigations are performed. You will also be asked to complete a questionnaire about your urinary symptoms. You will initially undergo the standard bladder pressure test as requested by your consultant. If you do not wish to proceed beyond this just tell a member of staff and you will be withdrawn from the study – it will not affect the care you will receive.

Following the standard pressure test, your bladder will be refilled with fluid via the catheter. The penile cuff will be placed around the penis. When you start to pass urine, the cuff will inflate until it interrupts the flow of urine. It will then relax and allow you to start passing urine again. This will happen a couple of times, until the bladder is completely empty. The bladder is filled once more, and the catheter is then removed. We will repeat the cuff test without the catheter in, and take some x-ray images of your bladder and water pipe during this part of the test. You will then be free to go home.

What happens with the results?

The results of the standard pressure test will be written into a report for your consultant as normal. Your consultant will then contact you with plans for further review in their clinic or to commence treatment of your underlying urinary problem.

The results generated for the research study will anonymous and confidential. No one will be able to identify you from the records we keep as part of the research. Once the study is complete the data collected will be analysed and published within medical journals, as well as presented at medical conferences. You can contact us to request the final study results if you so wish.

Are there any benefits from taking part?

There are no direct benefits to you in taking part in this study. The results of this study will hopefully help improve the investigation of men with similar problems in the future.

Are there any risks involved in taking part?

There are no serious risks involved in participating in this study. The risks of standard bladder pressure tests involve a small chance of seeing blood in your urine temporarily following the test, or developing a urine infection. If you feel like you have a urine infection on the day of your appointment, please let a member of staff know, as we would not proceed with the investigation, and reschedule your appointment once it is treated.

2% of men (2 per 100) find the penile cuff test uncomfortable, or may see blood in the urine following the test. The majority of men tolerate the test well.

The standard bladder pressure test requested by your doctor involves the use of x-rays to take images of the bladder and urine pipe. If you take part in this study, we would also like to take x-rays during the 2nd penile cuff test, to examine the effect the cuff has on the urine pipe as it inflates. These procedures use ionising radiation to form images of your body and provide your doctor with other clinical information. Ionising radiation can cause cell damage that may, after many years or decades turn cancerous.

We are all at risk of developing cancer during our lifetime. The normal risk is that this will happen to about 50% of people at some point in their life. The cumulative radiation exposure from these tests is considered small and is not likely to adversely affect you. The standard bladder pressure test would increase this risk by a very small amount (0.003%). Taking part in this study will only increase the risk slightly – the same as if we did your standard test twice.

What if there is a problem?

If you are unhappy about any aspect of this study, please speak to a member of staff who will do their best to address your concerns. If you remain unhappy you can contact the Patient Advice and Liaison Service (PALS) for further advice. Their contact details are listed at the end of this information sheet. In the unlikely event that you come to harm from taking part in this research study, or wish to make a formal complaint, you are able to take action through the normal NHS complaints procedures. If you are harmed due to someone's negligence then you may have grounds for legal action against the Newcastle upon Tyne Hospitals NHS Foundation Trust, but you may be required to pay your own legal costs.

Who has approved this study?

All research within the NHS is required to be reviewed by a Research Ethics Committee before it starts, to ensure it is conducted in an ethical manner, and complies with all appropriate legislation. Studies are only allowed to proceed once the Committee has given their approval. The Newcastle upon Tyne Hospital NHS Foundation Trust research and development department has also approved this project.

Who is funding the study?

The study has been organised by the Urology Research Group within the Newcastle upon Tyne Hospitals NHS Foundation Trust, who designed the penile cuff. Funding for this current

research project is derived from the royalties earned by the Trust from commercial sale of the penile cuff.

Will you contact my GP?

We will not directly contact your GP about this research project. The results of your bladder pressure test will be sent back to the referring urologist, and they will communicate the results to yourself and your GP as normal.

Contact Details

If you would like any further information, or wish to speak to the research team, please contact:

Miss Helen Morton, Urology Research Fellow
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Freeman Hospital
Freeman Road
Newcastle upon Tyne
NE7 7DN
TEL: 0191 2139602
Email: helen.morton@nuth.nhs.uk

The Patient Advice and Liaison Service (PALS) is a confidential service, and can be contacted as follows:

Freepost: RLTC-SGHH-EGXJ
North of Tyne PALS
The Old Stables
Grey's Yard
Morpeth
NE61 1QD
FREEPHONE: 0800 032 0202
Email: northoftynepals@nhct.nhs.uk