

Patient information sheet: HAARP study – qualitative

Home **A**ssessment of urinary voiding and storage function before and **A**fter **R**adical **P**rostatectomy for prostate cancer (IRAS ID: 242020)

Invitation

You are being invited to take part in a research study. Before you decide, it is important that you understand why the research is being done and what it will involve. Please take your time to read this information carefully and discuss it with others if you wish. Ask us if there is anything that is not clear or if you would like more information. Take your time to decide whether or not you wish to take part. Contact details for the researchers and the patient advice service are given at the end of this document.

Background

A prostate cancer diagnosis can be a difficult time of life for you and your loved ones. There is a lot of information to take in at the time of diagnosis. Your main thought when considering treatment options is likely to be getting rid of the cancer, and so you may think less about how your decision will affect your life later on.

Prostate cancer in the UK

Prostate cancer is the most common cancer in men in the UK. In 2014, there were over 40,000 new cases, and the number rises each year. Many of these men are treated by surgery to remove the whole prostate, an operation called a 'radical prostatectomy'. This has a good chance of cure, but it can cause side effects.

Radical prostatectomy side effects

Leakage of urine is the most common unwanted side effect of radical prostatectomy. Several large research studies have looked into this and measured how many men have leakage after surgery (ranging between 4% and 69%). Other studies have looked at how the surgery affects urinary symptoms. They found that symptoms such as a weak flow rate improved, but that patients felt they passed urine more often after the operation. Although patients have been asked about their symptoms, the effect on flow rate and the number of times they pass urine has never actually been measured.

What is the purpose of the study?

Alongside this interview study, we are carrying out a study where men record their urinary flow rates, volumes and frequencies at home using a portable device before and after surgery. We will use this information to create an easy to understand leaflet that can be given to patients who are thinking about having a radical prostatectomy. This way they can make a more informed decision about their treatment. The interview study will help us find out which issues are important to men so they can be included in the leaflet.

Why have I been invited to take part in the study?

You are considering or scheduled for radical prostatectomy surgery following a diagnosis of prostate cancer, or have had the surgery in the past.

Do I have to agree to take part?

No, taking part in this study is voluntary. If you would rather not take part, you don't have to tell us why and your care will not be affected. To help us plan future research work, we may ask you why you have decided not to take part, but you don't have to answer this question if you don't want to.

What will be involved if I take part?

You would take part in an interview lasting up to 30 minutes, either in person at a convenient time and place, or over the phone. You will be asked questions about your urinary symptoms before and, if applicable, after surgery, what relevant information you received, and whether there were any gaps in the information.

Audio recording

We would like to audio-record the interview so that we have an accurate record of what was said. This is an optional item on the consent form. We will ask you not to reveal any identifiable information during recording. If this happens, we will delete the identifiable information from the recording before sending it to a transcription company. If you don't want to be recorded, written notes will be taken instead.

Are there any risks to taking part in the study?

We believe there are no risks to taking part.

What are the benefits to me of taking part in the study?

There is no personal benefit in taking part in this study. The information we collect from this study may help to improve the care of men in a similar situation to you in the future. Travel expenses will be reimbursed for any additional visits to hospital for the purpose of the study.

Can I change my mind about taking part?

Yes, you can withdraw from the study at any time, without giving a reason, and your care will not be affected. Again, we may ask you why you have decided to withdraw, but you don't have to answer this question if you don't want to.

How will my information be stored?

Data from the study will be stored securely using a password-protected computer system. Identifiable data (your name and contact details) will be kept until 12 months after the study has ended, and then destroyed. It will be stored in a secure room on hospital premises.

What will you do with the results of the study?

The results of the study will be written into a report by the researchers. We also hope to publish them in scientific and medical journals, and present them at medical meetings and conferences. We will never publish any personal details about an individual, or anything that could allow them to be identified. We will be happy to supply a summary copy of the research findings after the end of the study. Please let us know if you would like to receive this.

Who has organised, reviewed and approved the study?

The study is being run by a team from The Newcastle upon Tyne Hospitals NHS Foundation Trust. The research has been reviewed and approved by the Health Research Authority, a Research Ethics Committee, and our local R&D department.

What if there is a problem about the study?

If you have any concerns about the study you should speak to the researcher, who will do their best to answer your queries. If you are still concerned you can contact the patient advice service (contact details below). To make a formal complaint you

can use the NHS complaints procedure, and details are available from the patient advice service.

If you feel you have been harmed during a research study, and that this is due to someone's negligence, you may have grounds to consider legal action against The Newcastle upon Tyne Hospitals NHS Foundation Trust, but you may have to pay.

Contact details

Lead researcher	Alison Bray Clinical Scientist (pre-registration) Medical Physics Royal Victoria Infirmary Newcastle upon Tyne NE1 4LP 0191 2823823 abray3@nhs.net
Patient advice	Patient Advice and Liaison Service (PALS) 0800 0320202 northoftynepals@nhct.nhs.uk Freepost: RLTC-SGHH-EGXJ North of Tyne PALS The Old Stables Grey's Yard Morpeth NE61 1QD

Statement on data protection and information governance

Newcastle Hospitals is both conducting and sponsoring this study. We will use your information in order to undertake this study and will act as data controller. This means that we are responsible for looking after your information and using it properly.

Your rights to access, change or move your information are limited, as we need to manage your information in specific ways in order for the research to be reliable and accurate. If you withdraw from the study, we will keep the information about you

that we have already obtained. To safeguard your rights, we will use the minimum personally-identifiable information possible.

We will use your name, hospital number, and phone number or address to contact you about the research study, make sure that relevant information about the study is recorded for your care, and oversee the quality of the study. The only people at Newcastle Hospitals who will have access to information that identifies you will be the researchers carrying out the interviews, and possibly members of the Joint Research Office (JRO) for the purpose of study audit. Other people involved in the study will not be able to find out your name, hospital number, phone number or address, or identify you.

We will keep identifiable information about you from this study for 6 years after it has ended. Non-identifiable information will be kept indefinitely.

You can find out more about how we use your information by visiting:

www.newcastle-hospitals.org.uk/about-us/freedom-of-information_how-we-use-information.aspx.