ISRCTN18295405 https://doi.org/10.1186/ISRCTN18295405

How is urination flow rate, volume and frequency affected in men who have had complete surgical removal of the prostate to treat prostate cancer?

Submission date
14/02/2020

Recruitment status
No longer recruiting

Registration date
28/04/2020

Overall study status
Completed

Last Edited
28/04/2020

Condition category
Urological and Genital Diseases

[_] Prospectively registered
[_] Protocol
[_] Statistical analysis plan
[_] Results
[_] Individual participant data
[_] Record updated in last year

Plain English Summary
Background and study aims
Men diagnosed with prostate cancer understandably often choose treatments that are most likely to get rid of the cancer. Surgical removal of the prostate can lead to changes in the frequency of passing urine and the amount of urine passed. These long-term changes can be bothersome and can lead to changes in lifestyle such as when and how much liquid is drunk. There is little information provided to men before surgery on how prostate removal might affect their urinary frequency and flow rate.
This study aims to measure the effects of prostate removal on urine flow and frequency. It will also interview men who have had prostate removal to find out about their symptoms, any changes to their lifestyle they have made and the information that was available to them before surgery. In addition, there will be interviews of men who are considering whether to have prostate removal to understand the information that would be most helpful. The results will help to guide creation of a leaflet to provide information at the point where a man is deciding about treatment for prostate cancer.

Who can participate?
Men who are about to have surgical prostate removal will participate in the part of the study that involves measuring their urinary function. Men who have already had their prostate removed and those who are considering it will participate in the interview part of the study.

What does the study involve?
In the urine function measurement part of the study, men will be given a Flowtaker device to measure their urine flow, amount and frequency. The device looks like a jug that stands on a sensor. For one week before surgery and 3 and 12 months after the surgery, participants will pass urine into the device when they are at home. They will also keep a diary of their liquid intake during the week and will fill out questionnaires on symptoms that might be affected by

prostate removal and their quality of life.
For the interview part, the participants will be interviewed for up to 30 minutes on their urinary symptoms and the information they received before their surgery.

What are the possible benefits and risks of participating?
There is no personal benefit from participating. Travel expenses associated with the study will be refunded. There are also no risks expected, though it might be inconvenient at times for men to pass urine into the Flowtaker device rather than a toilet.

Where is the study run from?
Newcastle upon Tyne Hospitals NHS Foundation Trust (UK)

When is the study starting and how long is it expected to run for?
December 2017 to August 2020

Who is funding the study?
The Urology Foundation (UK)

Who is the main contact?
Dr Alison Bray, abray3@nhs.net

Contact information

Type(s)
Scientific

Contact name
Dr Alison Bray

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Additional identifiers

EudraCT/CTIS number
Nil known

IRAS number
242020

ClinicalTrials.gov number

Nil known

Secondary identifying numbers
IRAS 242020

Study information

Scientific Title
Home Assessment of urinary voiding and storage function before and After Radical Prostatectomy for prostate cancer: setting patient expectations (The HAARP study)

Acronym
HAARP

Study hypothesis
The aim is to quantify the effect of radical prostatectomy on urinary function, including flow rates, voided volumes, and daytime and night-time frequency. This information will be used to develop patient literature to inform patients of changes following surgery.

Ethics approval required
Old ethics approval format

Ethics approval(s)
Approved 05/04/2018, South West - Cornwall & Plymouth Research Ethics Committee (Level 3, Block B,
Whitefriars, Lewins Mead, Bristol, BS1 2NT; +44 (0)207 104 8241; nrescommittee.southwest-cornwall-plymouth@nhs.net), ref:18/SW/0086

Study design
Observational qualitative study

Primary study design
Observational

Secondary study design
Qualitative

Study setting(s)
Hospital

Study type(s)
Quality of life

Participant information sheet
See additional files.

Condition
Urinary function following radical prostatectomy for prostate cancer

Interventions

40 men will complete a fluid intake diary and perform home uroflowmetry for 1 week using the Flowtaker device before surgery and at 3 and 12 months after radical prostatectomy for prostate cancer. They will also complete symptoms questionnaires that ask about their urinary function, bowel habits, sexual function, hormones, and general quality of life.

The researchers will also interview a small number of men to inform the development of a leaflet that can be given to patients who are thinking about having a radical prostatectomy in order to help them make an informed decision. The interview will ask about urinary symptoms before and after surgery, expectations of urinary symptoms following surgery, information received and changes to lifestyle.

Intervention Type
Procedure/Surgery

Primary outcome measure
1. Number of voids per 24-h period assessed using the Flowtaker device at baseline and 3 and 12 months after radical prostatectomy
2. Number of voids per night assessed using the Flowtaker device at baseline and 3 and 12 months after radical prostatectomy
3. Urinary flow rate assessed using the Flowtaker device at baseline and 3 and 12 months after radical prostatectomy
4. Voided volume assessed using using the Flowtaker device at baseline and 3 and 12 months after radical prostatectomy

Secondary outcome measures
1. Urinary symptoms measured by the ICIQ-MLUTS questionnaire at baseline and 3 and 12 months after radical prostatectomy
2. General well-being measured by the FACT-P questionnaire at baseline and 3 and 12 months after radical prostatectomy
3. Qualitative analysis of interviews

Overall study start date
18/12/2017

Overall study end date
31/08/2020

Eligibility

Participant inclusion criteria
Men undergoing radical prostatectomy for prostate cancer

Participant type(s)
Patient

Age group
Adult

Sex
Male

Target number of participants
40

Participant exclusion criteria
1. Men with an indwelling urinary catheter
2. Men who carry out intermittent self-catheterisation
3. Men unable or unwilling to void in a standing position

Recruitment start date
10/05/2018

Recruitment end date
31/05/2020

Locations

Countries of recruitment
England

United Kingdom

Study participating centre
Freeman Hospital
The Newcastle upon Tyne Hospitals NHS Foundation Trust
Freeman Road
High Heaton
Newcastle upon Tyne
United Kingdom
NE7 7DN

Study participating centre
Southmead Hospital
North Bristol NHS Trust
Southmead Road
Westbury-on-Trym
Bristol
United Kingdom
BS10 5NB

Sponsor information

Organisation
Newcastle upon Tyne Hospitals NHS Foundation Trust

Sponsor details
Newcastle Joint Research Office
1st Floor Regent Point
Regent Farm Road
Newcastle upon Tyne
England
United Kingdom
NE3 3HD
+44 (0)191 282 5959
nuth.nuthsponsorship@nhs.net

Sponsor type
Hospital/treatment centre

Website
https://newcastlejro.com

ROR
https://ror.org/05p40t847

Funder(s)

Funder type
Charity

Funder Name
The Urology Foundation

Results and Publications

Publication and dissemination plan
Planned outputs:
1. A report of quantitative results.
2. A report of qualitative results.
3. An information leaflet informing patients of the effect of radical prostatectomy on urinary function.
4. Publications, abstracts and conference submissions.

Intention to publish date
31/12/2020

Individual participant data (IPD) sharing plan
The datasets generated and/or analysed during this study will be included in the subsequent results publication.

IPD sharing plan summary

Other

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
Participant information sheet	version v2.0	03/04/2018	28/04/2020	No	Yes
Participant information sheet	version v1	02/05/2019	28/04/2020	No	Yes
HRA research summary			28/06/2023	No	No