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Development and evaluation of a patient-reported instrument to monitor oncological and functional outcomes after radical prostatectomy: the true NTH Post Surgery programme

Submission date
06/11/2015

Recruitment status
No longer recruiting

Registration date
23/11/2015

Overall study status
Completed

Last Edited
24/11/2016

Condition category
Cancer

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

Plain English summary of protocol
Not provided at time of registration

Contact information

Type(s)
Scientific

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Additional identifiers

EudraCT/CTIS number

IRAS number

ClinicalTrials.gov number

Secondary identifying numbers
CTU/2015/182

Study information

Scientific Title
True NTH UK post surgical follow up: development and evaluation of a patient-reported instrument to monitor oncological and functional outcomes after radical prostatectomy

Acronym
True NTH UK Post Surgical Follow up

Study objectives
Prostate cancer is the most common cancer in men in the UK, with over 40,000 new diagnoses every year. The most recent estimates suggest there are over 250,000 men in the UK living with and beyond a diagnosis of prostate cancer, and this has been predicted to increase to 831,000 by 2040. Earlier cancer detection, but also effective treatments, are contributing to these increasing survival rates. Radical prostatectomy is a commonly performed operation to treat localised prostate cancer. The National Cancer Intelligence Network reports that around 10% of men with a new diagnosis of prostate cancer have radical prostatectomy.

However, men who choose radical surgery for prostate cancer can experience side effects, including urine leakage and problems with erections. A recent national UK survey has shown that men want to have greater understanding of, and support for these side effects, both before they choose a treatment, and when they are dealing with side effects after treatment. In particular, in the 2013 survey only 64% of men who had prostate cancer treatment said that they were told about possible future side effects of treatment. One of the difficulties in telling men about the possible side effects after prostate cancer surgery is that these side effects will depend upon the urinary and sexual function that a man has prior to the operation, as well as on the details of the operation itself, which is influenced by the location and aggressiveness of the prostate cancer.

A monitoring instrument (MSK instrument) has been developed in the US and adapted for web-based use (“STAR”). It is used to collect patient-reported outcome measures (PROMs) before and after radical prostatectomy in order to monitor functional recovery in individual men. It has been suggested that men find it helpful to keep track of their progress over time and to compare it to that of men like them, although confirmatory data are awaited. Work in Germany has also demonstrated that this type of monitoring after prostatectomy based on patient-reported information can be used by surgeons to identify and support best practice. In addition, such an instrument could potentially be used as a prognostic tool predicting outcomes after radical prostatectomy. This type of prognostic information may inform men who are deciding whether or not they want to undergo a radical prostatectomy.

The True NTH UK Post Surgical Follow up Programme will focus on using patient reported outcome measures (PROMs) to assess the extent and timeline for recovery of urinary and sexual function after radical surgery for prostate cancer. A new instrument will be developed for radical prostatectomy that can be used with men in the UK to monitor their recovery in the first 12 months after surgery. It is envisaged that the PROMs data will be used in clinical practice to monitor progress in outcomes for individual patients. The programme will also allow a comparison of results of surgeons and hospitals against appropriate benchmarks for urinary and sexual outcomes after radical prostatectomy.

Ethics approval required
Old ethics approval format

Ethics approval(s)
National Research Ethics Committee South Central - Hampshire B, 07/09/2015 , ref: 15/SC/0451

Study design
Observational and cross-sectional study. This is a multi-centre study.

Primary study design
Observational

Secondary study design
Cross sectional study

Study setting(s)
Hospital

Study type(s)
Quality of life

Participant information sheet
Not available in web format, please use contact details to request a participant information sheet

Health condition(s) or problem(s) studied
Prostate cancer

Interventions
Radical prostatectomy

Intervention Type

Primary outcome measure
The primary outcome of this study is the new monitoring tool. This study aims to address the following:
1. To develop a new monitoring tool that is suitable for the routine collection of patient reported signs and symptoms, functional status, and health related quality of life before and after radical prostatectomy in the UK
2. To assess to what extent the preoperative results captured with the new monitoring tool can be used – together with other patient characteristics, including comorbidity

and disease characteristics – to predict patient reported functional outcomes (e.g. urinary and sexual function) 12 months after radical prostatectomy
3. To determine appropriate 'benchmarks' for urinary and sexual outcomes based on the new monitoring tool against which outcomes of radical prostatectomy surgery can be compared in the UK.
4. To develop a network of radical prostatectomy surgeons who can reflect on the surgical and patient reported outcome data to identify any areas of surgical practice which can be adopted more widely to improve outcomes for men
5. To use the tool to predict patient reported functional outcomes to inform patient led decision making for those men who have a choice of treatment strategies for localized prostate cancer

Secondary outcome measures
There are no secondary outcome measures.

Overall study start date
07/09/2015

Completion date
31/03/2017

Eligibility

Key inclusion criteria
1. A diagnosis of prostate cancer and scheduled to have radical prostatectomy
2. Access to the internet
3. An understanding of the English language sufficient to understand and complete on line CRFs
4. An understanding of the English language sufficient to understand written and verbal information about the trial and consent process
5. Signed informed consent

Participant type(s)
Patient

Age group
Adult

Sex
Male

Target number of participants
1000

Key exclusion criteria
Men who are unable to give informed consent.

Date of first enrolment
13/11/2015

Date of final enrolment
31/03/2017

Locations

Countries of recruitment
England

United Kingdom

Study participating centre
University College London Hospitals NHS Foundation Trust
250 Euston Road
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Study participating centre
North Bristol NHS Trust
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Study participating centre
The Newcastle upon Tyne Hospitals NHS Foundation Trust
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The Royal Marsden NHS Foundation Trust
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Study participating centre
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Study participating centre
South West London And St George's Mental Health NHS Trust
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Blackshaw Road
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Sponsor information

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Sponsor type
University/education

Website
www.ucl.ac.uk/ctg

ROR
https://ror.org/02jx3x895

Funder(s)

Funder type
Charity

Funder Name
Prostate Cancer UK

Alternative Name(s)
Prostate Cancer, Prostate Action, ProstateUK, prostatecanceruk

Funding Body Type
Private sector organisation

Funding Body Subtype
Other non-profit organizations

Location
United Kingdom

Results and Publications

Publication and dissemination plan
Presentations and publications arising directly from the pre-planned analyses will be the responsibility of the project team.

Other members of the medical and scientific community will be encouraged to submit requests for new analyses of the data set. However, the raw data will remain in the custodianship of the True NTH Post Surgical Follow up Study Operations Group, apart from the transfer of anonymised data to the project team for pre-determined analyses.

Any publications arising from the study will be made publicly available at www.ctgparticipants.org

Intention to publish date

Individual participant data (IPD) sharing plan

IPD sharing plan summary
Available on request

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
HRA research summary			28/06/2023	No	No