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Assessing the sexual consequences of focal therapy for localised prostate cancer

Submission date
16/09/2020

Recruitment status
Stopped

Registration date
18/09/2020

Overall study status
Stopped

Last Edited
23/11/2021

Condition category
Cancer

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

Plain English summary of protocol

Background and study aims
Prostate cancer is a form of cancer that develops in the prostate gland. Focal therapy involves treating just the cancer, while leaving the rest of the prostate and surrounding tissue intact. The aim of this study is to collect information about changes in men's sexual function after focal therapy to provide men with accurate information they can use when deciding which treatment to choose.

Who can participate?
Men who were treated for prostate cancer with irreversible electroporation (IRE) in the past 2 years can be enrolled in the retrospective arm of the study. Men who will be treated for prostate cancer with focal therapy with high-intensity focused ultrasound (HIFU), cryotherapy or IRE can take part in the prospective arm.

What does the study involve?
Men in the retrospective arm will be asked to fill in questionnaires about the quality of their erections and ejaculation. A telephone interview will be organised to collect more in-depth data about the changes in their sexual function after the treatment (covering topics such as erection, ejaculation, orgasm, changes in the size or shape of the penis, etc).
Men in the prospective arm will have an evaluation before surgery using the same questionnaires, and a first telephone interview to record their expectations. Another evaluation including questionnaires and a second telephone interview will be scheduled 3 months after surgery to collect more in-depth data about the changes in their sexual function after the treatment (covering topics such as erection, ejaculation, orgasm, changes in the size or shape of the penis, etc).

What are the possible benefits and risks of participating?
The researchers will try to accommodate patients' schedule to minimise the inconvenience in taking part in the interviews. Participants may worry about experiencing some discomfort discussing intimate matters with a researcher. The study team will make sure that the training of the interviewer and interview methods used allow men to feel at ease during the interview. Participants will receive compensation in the form of £40 vouchers and will help future patients benefit from more accurate information before treatment.

Where is the study run from?
University College London (UK)

When is the study starting and how long is it expected to run for?
April 2020 to February 2022 (updated 17/05/2021, previously: August 2021)

Who is funding the study?
Angiodynamics (USA)

Who is the main contact?
Gaelle Fiard
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Contact information

Type(s)
Scientific

Contact name
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Additional identifiers

Integrated Research Application System (IRAS)
278558

Study information

Scientific Title
Sexual Assessment after Focal therapy with various Energy sources (SAFE): a mixed-methods study

Acronym
SAFE

Study objectives
Focal therapy has arisen as a promising tissue-preserving treatment option for men with localised prostate cancer, offering to better preserve men's genito-urinary function. However, most of the evaluation of function has taken place at a relatively high, non-granular level. However, most of the data used to provide informed consent for patients is obtained from retrospective – usually single-centre – series, or derived from prospective studies whose primary outcome was oncological. The aim of the SAFE study is to address this need by collecting in-depth details of men's sexual function after focal therapy with various energy sources, using qualitative research methods and validated questionnaires.

Ethics approval required
Old ethics approval format

Ethics approval(s)
Approved 02/09/2020, North West - Greater Manchester West Research Ethics Committee (Barlow House 3rd Floor, 4 Minshull Street, Manchester M1 3DZ, +44 (0)2071048285; gmwest.rec@hra.nhs.uk), REC ref: 20/NW/0335

Study design
Mixed-methods study

Primary study design
Observational

Study type(s)
Quality of life

Health condition(s) or problem(s) studied
Localised prostate cancer treated with focal therapy

Interventions
1. Self-administered validated questionnaires
2. Semi-structured telephone interviews

Men in the retrospective arm will be asked to fill in validated questionnaires exploring and quantifying the quality of their erections and ejaculation. A telephone interview will be organised to collect more in-depth data about the evolution of their sexual function after the treatment (covering topics such as erection, ejaculation, orgasm, changes in the size or shape of the penis, etc).

Men in the prospective arm will have a baseline evaluation before surgery, using the same questionnaires, and a first telephone interview to record their expectations. Another evaluation including questionnaires and a second telephone interview will be scheduled 3 months after surgery to collect more in-depth data about the evolution of their sexual function after the treatment (covering topics such as erection, ejaculation, orgasm, changes in the size or shape of the penis, etc).

Intervention Type
Behavioural

Primary outcome(s)

Qualitative sexual outcomes gathered using semi-structured telephone interviews at 3 months after focal therapy (prospective cohort)

Key secondary outcome(s))
1. Preoperative patients' expectations assessed using semi-structured telephone interviews at baseline (or before treatment)
2. Qualitative sexual outcomes gathered using semi-structured telephone interviews at various time points ranging from 6 months and 24 months after surgery (retrospective arm - the researchers will select patients to cover as many timepoints as possible but don’t know yet which ones precisely)
3. Erectile function measured by IIEF-15 at baseline and 3 months
4. Ejaculatory function measured by MSHQ-EjD-SF at baseline and 3 months

Completion date
28/02/2022

Reason abandoned (if study stopped)
Lack of staff/facilities/resources

Eligibility

Key inclusion criteria
Retrospective cohort:
1. Men treated with focal IRE in the last 24 months agreeing to be approached after receiving the invitation letter
2. Preoperative normal sexual function (retrospective)
3. Signed informed consent by the patient

Prospective cohort:
1. Men with a histological diagnosis of prostate cancer on trans-rectal or transperineal template prostate biopsies
2. Gleason score ≤7
3. Clinical stage ≤T2cNoMo (radiological T3a allowed)
4. Serum PSA ≤15ng/ml
5. Local staging imaging as per guidelines to demonstrate localised disease (this may include MRI, CT, bonescan or functional imaging)
6. MRI-visible unilateral or anterior disease accessible to focal HIFU, cryotherapy or IRE
7. Baseline potency with erections sufficient for penetration
8. Signed informed consent by the patient

Participant type(s)
Patient

Healthy volunteers allowed
No

Age group
Adult

Sex

Male

Key exclusion criteria
Retrospective cohort:
1. Men with preoperative (remembered) altered sexual function or no sexual activity
2. Salvage treatment
3. Non-English readers and speakers
4. Vulnerable men unable to provide informed consent

Prospective cohort:
1. Men with baseline erectile dysfunction and erections insufficient for penetration
2. Men who had prostate surgery for cancer control e.g., radical prostatectomy, HIFU, cryosurgery, photodynamic therapy
3. Men undergoing whole-gland treatment
4. Non-English readers and speakers
5. Vulnerable men unable to provide informed consent

Date of first enrolment
25/09/2020

Date of final enrolment
30/11/2021

Locations

Countries of recruitment
United Kingdom

England

Study participating centre
University College London Hospitals NHS Foundation Trust
250 Euston Road
London
United Kingdom
NW1 2PG

Study participating centre
London Urology Specialists
Emmanuel Kaye House
37 Devonshire Street
London
United Kingdom
W1G 6QA

Sponsor information

Organisation
University College London

ROR
https://ror.org/02jx3x895

Funder(s)

Funder type
Industry

Funder Name
AngioDynamics

Results and Publications

Individual participant data (IPD) sharing plan
The datasets generated during and/or analysed during the current study are/will be available upon request from Gaelle Fiard (g.fiard@ucl.ac.uk). Anonymised data can be made available and patients will be consenting to it. Anonymised scores on validated questionnaires and transcripts can be obtained for verification purposes.

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
Participant information sheet	version V2.0	28/08/2020	08/10/2020	No	Yes
Participant information sheet	version V2.0	28/08/2020	08/10/2020	No	Yes
Protocol file	version V1.0	29/06/2020	08/10/2020	No	No