

Assessing the sexual consequences of focal therapy for localised prostate cancer

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|----------------------------------------|----------------------------------------|--------------------------------------------------------------------------------------------------------------|
| Submission date 16/09/2020 | Recruitment status Stopped | <input checked="" type="checkbox"/> Prospectively registered <input checked="" type="checkbox"/> Protocol |
| Registration date 18/09/2020 | Overall study status Stopped | <input type="checkbox"/> Statistical analysis plan <input type="checkbox"/> Results |
| Last Edited 23/11/2021 | Condition category Cancer | <input type="checkbox"/> Individual participant data <input type="checkbox"/> 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
g.fiard@ucl.ac.uk

Contact information

Type(s)
Scientific

Contact name
Mrs Gaelle Fiard

ORCID ID
<https://orcid.org/0000-0003-3049-5318>

Contact details
Division of Surgery and Interventional Science
University College London
3rd Floor, Charles Bell House
43-45 Foley Street
London
United Kingdom
W1W 7TS
+44 (0)7568764334
g.fiard@ucl.ac.uk

Additional identifiers

Clinical Trials Information System (CTIS)
Nil known

Integrated Research Application System (IRAS)
278558

ClinicalTrials.gov (NCT)
Nil known

Protocol serial number
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 $\leq T2cNoMo$ (radiological T3a allowed)
4. Serum PSA $\leq 15ng/ml$
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 Gaele 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