

An evaluation of Focal ablation therapy using High-Intensity Focused Ultrasound in the treatment of localised adenocarcinoma of the prostate

Submission date 30/08/2007	Recruitment status No longer recruiting	<input type="checkbox"/> Prospectively registered
		<input type="checkbox"/> Protocol
Registration date 03/07/2008	Overall study status Completed	<input type="checkbox"/> Statistical analysis plan
		<input type="checkbox"/> Results
Last Edited 26/10/2022	Condition category Cancer	<input type="checkbox"/> Individual participant data
		<input type="checkbox"/> Record updated in last year

Plain English summary of protocol

<https://www.cancerresearchuk.org/about-cancer/find-a-clinical-trial/a-trial-looking-at-high-intensity-focused-ultrasound-to-treat-areas-of-prostate-cancer-contained-in-the-prostate-gland>

Contact information

Type(s)

Scientific

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Additional identifiers

Study information

Scientific Title

An evaluation of Focal ablation therapy using High-Intensity Focused Ultrasound in the treatment of localised adenocarcinoma of the prostate

Acronym

Focal-HIFU

Study objectives

Do men with early localised prostate cancer (T2c N0 M0 or less), when treated with focal ablation of all cancer foci and a margin of 5 mm normal tissue, using the high-intensity focused ultrasound (HIFU) Sonablate® 500, experience less harm (fewer treatment related toxicities) when compared to conventional whole gland therapies (either radical radiation therapy or surgery)? In addition, is treatment in a focal manner feasible (as laid out in the treatment protocol below) in a manner that allows destruction of those cancer areas?

Ethics approval required

Old ethics approval format

Ethics approval(s)

Joint University College London (UCL)/University College London Hospitals (UCLH) Committees on the Ethics of Human Research (Committee A), ref: 07/Q0505/37

Study design

Interventional phase II single-arm proof of concept single-centre trial

Primary study design

Interventional

Study type(s)

Treatment

Health condition(s) or problem(s) studied

Localised prostate cancer

Interventions

All participants will be treated with HIFU using the Sonablate 500® (Focused Surgery, USA) under general anaesthesia. Only areas of cancer as identified by template biopsies will be treated with a margin of 5 mm normal tissue.

Follow-up:

1. MRI at 2 weeks and 6 months
2. Transrectal biopsy at 6 months
3. Clinic visits at 1 month, 3, 6, 9 and 12 months
4. PSA at all clinic visits

Intervention Type

Other

Phase

Phase II

Primary outcome(s)

To determine patient acceptability, feasibility, and side-effect profile by evaluating:

1. Recording of adverse events
2. Urinary symptoms and erectile function will be assessed at each visit with the following questionnaires:
 - 2.1. International Index of Erectile Function-15 [IIEF-15]
 - 2.2. International Prostate Symptom Score [IPSS] and IPSS - Quality of Life (IPSS-QoL)
 - 2.3. Functional Assessment of Cancer Therapy - Prostate (FACT-P)
 - 2.4. Continence questionnaires

Key secondary outcome(s)

To determine the effectiveness of therapy by:

1. Post-treatment biopsies of treated areas at 6 months
2. Post-treatment MRI to evaluate area of necrosis within two weeks and at 6 months
3. Measurement of PSA at each follow-up visit and estimated measurement of time to PSA nadir
4. Recording the need for secondary or adjuvant treatment following therapy

Completion date

30/05/2009

Eligibility

Key inclusion criteria

1. Men aged 45 - 80 years
2. Histological diagnosis of prostate adenocarcinoma
3. Gleason grade total 7 or less (patterns 3+4 or 4+3 or less acceptable)
4. Cancer prostate-confined only (bilateral or unilateral)
5. Serum prostate specific antigen (PSA) less than or equal to 15 ng/mL
6. A life expectancy of 5 years or more
7. Prostate volume less than or equal to 40 cc or maximum anterior-posterior length less than or equal to 40 mm
8. Has had multi-sequence magnetic resonance imaging (ms-MRI) and transperineal template 5 mm spaced biopsies in the 6 months prior to recruitment
9. All malignant areas are treatable by focal ablation so that approximately 50% of prostate tissue is destroyed and at least one neurovascular bundle is preserved
10. Signed informed consent form by patient

Participant type(s)

Patient

Healthy volunteers allowed

No

Age group

Adult

Sex

Male

Total final enrolment

Key exclusion criteria

1. Men who have received androgen suppression within previous 6 months
2. Men who have had previous radiation therapy for prostate cancer
3. Men treated with chemotherapy for prostate cancer
4. Men with evidence of metastatic disease
5. Men with latex allergies
6. Men who have undergone prior significant rectal surgery preventing insertion of transrectal probe
7. Men with intraprostatic calcifications making HIFU of focal areas of cancer untreatable
8. Men who have undergone previous transurethral resection of the prostate or laser prostatectomy in the 5 years prior to recruitment
9. Men who have undergone previous HIFU, cryosurgery, thermal or microwave therapy to the prostate at any point prior to recruitment
10. American Society of Anaesthesiology grades III - IV
11. Men not fit for general anaesthesia or regional anaesthesia as assessed by Consultant Anaesthetist
12. Men unable to have MRI scanning (e.g., severe claustrophobia, permanent cardiac pacemaker, metallic implant likely to contribute significant artifact to images)

Date of first enrolment

01/06/2007

Date of final enrolment

30/05/2009

Locations

Countries of recruitment

United Kingdom

England

Study participating centre

University College London Hospitals NHS Foundation Trust

London

United Kingdom

NW1 2BU

Sponsor information

Organisation

University College London Hospitals NHS Foundation Trust (UK)

ROR

https://ror.org/042fqyp44

Funder(s)

Funder type

Charity

Funder Name

St Peter's Research Trust (UK)

Funder Name

Pelican Cancer Foundation (UK)

Alternative Name(s)

Pelicanfon

Funding Body Type

Private sector organisation

Funding Body Subtype

Trusts, charities, foundations (both public and private)

Location

United Kingdom

Results and Publications

Individual participant data (IPD) sharing plan

Not provided at time of registration

IPD sharing plan summary

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
Plain English results			26/10/2022	No	Yes