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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

Registration date
03/07/2008

Overall study status
Completed

Last Edited
26/10/2022

Condition category
Cancer

[_] Prospectively registered
[_] Protocol
[_] Statistical analysis plan
[_] Results
[_] Individual participant data
[_] 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

EudraCT/CTIS number

IRAS number

ClinicalTrials.gov number

Secondary identifying numbers
N/A

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

Secondary study design
Non randomised study

Study setting(s)
Hospital

Study type(s)
Treatment

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

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 measure
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

Secondary outcome measures
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

Overall study start date
01/06/2007

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

Age group
Adult

Sex
Male

Target number of participants
33

Total final enrolment
42

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
England

United Kingdom

Study participating centre
University College London Hospitals NHS Foundation Trust
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Sponsor information

Organisation
University College London Hospitals NHS Foundation Trust (UK)

Sponsor details
Research and Development Office
Institute of Child Health
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Sponsor type
University/education

Website
http://www.uclh.nhs.uk/Researchers/RandD+Directorate/

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)

Funding Body Type
Private sector organisation

Funding Body Subtype
Trusts, charities, foundations (both public and private)

Location
United Kingdom

Results and Publications

Publication and dissemination plan
Not provided at time of registration

Intention to publish date

Individual participant data (IPD) sharing plan
Not provided at time of registration

IPD sharing plan summary
Not provided at time of registration

Study outputs

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