

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

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<b>Registration date</b> 03/07/2008	<b>Overall study status</b> Completed	<input type="checkbox"/> Statistical analysis plan <input type="checkbox"/> Results
<b>Last Edited</b> 26/10/2022	<b>Condition category</b> 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

### Contact name

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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  
London  
United Kingdom  
NW1 2BU

## Sponsor information

**Organisation**

University College London Hospitals NHS Foundation Trust (UK)

**Sponsor details**

Research and Development Office  
Institute of Child Health  
30 Guilford Street  
London  
England  
United Kingdom  
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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?
<a href="#">Plain English results</a>			26/10/2022	No	Yes