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An evaluation of hemi-ablation therapy using high-intensity focused ultrasound (HIFU) in the treatment of localised adenocarcinoma of the prostate

Submission date
17/03/2006

Registration date
12/04/2006

Last Edited
26/10/2018

Recruitment status
No longer recruiting

Overall study status
Completed

Condition category
Cancer

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

Plain English summary of protocol
http://cancerhelp.cancerresearchuk.org/trials/a-trial-looking-at-high-intensity-focussed-ultrasound-for-prostate-cancer-contained-in-one-half-of-the-prostate-gland

Contact information

Type(s)
Scientific

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Additional identifiers

EudraCT/CTIS number

IRAS number

ClinicalTrials.gov number
NCT00561262

Secondary identifying numbers
N/A

Study information

Scientific Title
An evaluation of hemi-ablation therapy using high-intensity focused ultrasound (HIFU) in the treatment of localised adenocarcinoma of the prostate

Study objectives
Over 30,000 men are newly diagnosed with prostate cancer every year. Over two-thirds of these men have a localised disease. Men with localised prostate cancer (CaP) currently have to choose between active surveillance and radical therapy (surgery or radiotherapy). Such treatments carry significant side effects with high rates of impotence, incontinence and changes in bowel function. The best evidence we have shows the difference between these two very different approaches is not large in terms of preventing an individual from dying of prostate cancer within a 10 year period - 14% mortality for active surveillance, compared to a rate of 9% for men who had radical prostatectomy. We wish to challenge the prevailing assumption that all men need the whole gland treated in order to benefit from cancer control. In men with cancer localised to just one side of the prostate, can we achieve similar cancer control without exposure to the harms traditionally associated with radical therapies?

Aims:
This study aims to evaluate the use of hemi-ablation using high intensity focused ultrasound (HIFU) in unilateral, localised CaP. Men treated with hemi-ablation will be evaluated for:
1. Less harm: fewer treatment-related toxicities
2. Early benefit: absence of tumour on post-therapy biopsy
3. Late benefit: absence of biochemical prostate specific antigen (PSA) progression

Outline plan:
This is a phase I trial with two stages. Forty men who have unilateral disease as shown with standard transrectal ultrasound (TRUS)-guided biopsies will be initially recruited. They will undergo verification of true unilateral CaP with multi-sequence magnetic resonance imaging (ms-MRI) (contrast enhanced, spectroscopy and diffusion MRI) and transperineal template-guided biopsies. We anticipate only 20 men will proceed to have HIFU hemi-ablation of the side with cancer. Our participation in the European multicentre trial evaluating whole gland ablation using HIFU has demonstrated our ability to ablate prostate tissue using the Sonoblate® HIFU in a safe and effective manner. To date, our groups patients have no cancer on post treatment biopsies in this study.

Follow-up will be compared to pre-treatment parameters and will include the following:
1. Clinic visits at 1, 3, 6, 12, 18 and 24 months with standard questionnaires for assessing erectile and urinary function
2. Serum PSA measurements with evaluation of PSA kinetics
3. Post-treatment MRI to assess treatment effect
4. TRUS biopsies (local anaesthetic) at six months to verify absence of cancer

Ethics approval required
Old ethics approval format

Ethics approval(s)

Ethics approval not yet received as of 12/04/06

Study design
Interventional phase I safety and feasibility trial

Primary study design
Interventional

Secondary study design
Non randomised controlled trial

Study setting(s)
Hospital

Study type(s)
Treatment

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

Health condition(s) or problem(s) studied
Localised prostate carcinoma

Interventions
Stage 1: verification that men with unilateral cancer, as demonstrated by TRUS-guided biopsies, have true unilateral disease. Although initially it was mooted that we could rely on just the TRUS biopsy result to define a localised, unilateral prostate cancer population, a recent evidence has shown that only half of these men have true unilateral disease if transperineal biopsies are taken. As well as transperineal template-guided biopsies, multi-sequence MRI will be carried out: the combination will give us an accuracy of over 95%. Forty patients will be recruited and we anticipate about 20 will have true unilateral prostate cancer. The patients who have bilateral disease will be offered current standard of care at University College London Hospital (UCLH) or their referring centre.

Stage 2: treatment using Sonablate® 500 HIFU to ablate the positive side only. Follow-up will be with regular clinic visits, questionnaires, blood PSA, post-treatment MRI to assess effect and, TRUS prostate biopsy at six months post-treatment to ensure absence of tumour on both sides. All adverse events will be recorded and treatment-related harm will be assessed with standard questionnaires on erectile function, urinary function and quality of life. Follow-up will be at day 2, day 7 and 1, 3, 6, 12, 18 and 24 months.

Intervention Type
Other

Phase
Phase I

Primary outcome measure
To determine feasibility, patient acceptability and side-effect profile of using Sonablate® 500 HIFU to hemiablate the prostate gland in localised, unilateral prostate cancer

Secondary outcome measures
To determine the effectiveness of therapy by assessing cancer control in the following ways:
1. Biochemical (PSA) progression-free survival
2. Proportion of men with negative biopsies post-treatment

Overall study start date
01/06/2006

Completion date
01/12/2008

Eligibility

Key inclusion criteria
Inclusion criteria for verification stage 1
1. Men aged under 80 years
2. Histological diagnosis of prostate adenocarcinoma
3. Cancer prostate-confined only
4. Cancer confined to one lobe as defined by TRUS biopsy
5. Serum PSA less than or equal to 15 ng/ml
6. A life expectancy of five years or more
7. Prostate volume less than or equal to 40 cc
8. Signed informed consent form by patient for multi-sequence MRI and transperineal biopsy
9. Patient willing to proceed to stage 2 if stage 2 inclusion/exclusion criteria fulfilled

Stage 2 HIFU hemi-ablation treatment inclusion criteria:
1. Men with unilateral prostate adenocarcinoma after having undergone verification of unilateral disease in stage 1 of this trial or verification (with ms-MRI and transperineal template biopsies outside of this trial)
2. The following inclusion criteria for stage 1 are to be re-assessed after stage 1: 1, 2, 3, 6, 7
3. Signed informed consent by patient for HIFU hemiablation treatment

Participant type(s)
Patient

Age group
Adult

Sex
Male

Target number of participants
40 in stage 1, 20 in stage 2

Key exclusion criteria
Exclusion criteria for verification stage 1:
1. Men who have received androgen suppression within previous six 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 greater than or equal to 10 mm in size
8. Men who have undergone previous transurethral resection of the prostate or laser prostatectomy
9. Men who have undergone previous HIFU, cryosurgery, thermal or microwave therapy to the prostate
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 artefact to images)

Exclusion criteria for treatment stage 2:
1. All exclusion criteria for stage 2 are to be verified again before treatment.

Date of first enrolment
01/06/2006

Date of final enrolment
01/12/2008

Locations

Countries of recruitment
England

United Kingdom

Study participating centre
The Institute of Urology
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Sponsor information

Organisation
University College London Hospitals (UCLH) NHS Foundation Trust (UK)

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Sponsor type
Hospital/treatment centre

Website
http://www.uclh.nhs.uk

ROR
https://ror.org/042fqyp44

Funder(s)

Funder type
Charity

Funder Name
Pelican Cancer Foundation (UK) - North Hampshire Hospital

Results and Publications

Publication and dissemination plan
Not provided at time of registration

Intention to publish date

Individual participant data (IPD) sharing plan

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				No	Yes
Results article	results	01/04/2011		Yes	No