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Magnetic nanoparticle thermoablation - retention and maintenance in prostate

Submission date	Recruitment status	[ ] Prospectively registered
17/12/2013	No longer recruiting	[ ] Protocol
Registration date	**Overall study status**	[ ] Statistical analysis plan
17/12/2013	Completed	[ ] Results
Last Edited	**Condition category**	[ ] Individual participant data
09/08/2019	Cancer	[ ] Record updated in last year

Plain English summary of protocol
http://www.cancerresearchuk.org/cancer-help/trials/a-study-looking-nanoparticles-heat-destroy-prostate-cancer-magnablate-i-trial

Contact information

Type(s)
Scientific

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Additional identifiers

EudraCT/CTIS number

IRAS number

ClinicalTrials.gov number
NCT02033447

Secondary identifying numbers
15516

Study information

Scientific Title
MAGnetic NAnoparticle thermoaBLATion - retention and maintenance in prostatE: a Phase 0 study in men (MAGNABLATE I trial)

Acronym
MAGNABLATE I

Study objectives
This Phase 0 dose escalation safety trial aims to evaluate the retention of magnetic nanoparticles in the prostate.

The primary study objectives are:-
1. To conduct a dose escalation safety trial of magnetic nanoparticles injected into the prostates of men prior to cystoprostatectomy.
2. To conduct a dose escalation safety trial of magnetic nanoparticles injected into the prostates of men prior to prostatectomy.
3. To evaluate ex-vivo prostates with a special marker to determine the retention and distribution of the magnetic nanoparticles in relation to the intended target area at time of injection.

The secondary study objectives are:-
To evaluate the anatomical distribution of magnetic nanoparticles compared with injection site in prostate assessed by both Perls staining and postoperative imaging (MRI and CT) of the ex vivo tissue.

Ethics approval required
Old ethics approval format

Ethics approval(s)
First MREC approval date 17/09/2013, ref: 13/LO/1233

Study design
Non-randomised interventional treatment 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
Topic: National Cancer Research Network; Subtopic: Prostate Cancer; Disease: Prostate

Interventions
The trialists are aiming for a minimum of 60% of injected nanoparticles to be retained within the prostate over an average of first 6 patients. They aim to recruit a representative group of men who have overt cancer lesions as well as overt benign areas for injection.
They are aiming for the following:
Minimum number of benign prostate lobes 12
Minimum number of malignant lobes 6
Men undergoing Radical Cystoprostatectomy and Radical Prostatectomy will be recruited until the above numbers are fullfilled.

Injection of nano-particles, Pre-operative preparation: This procedure will be carried out just prior to the surgery (cystoprostatectomy or prostatectomy). The patient will be admitted on the morning of the procedure. The patient will be asked to sign the hospital procedure specific consent form.
Procedure set-up: Intravenous antibiotics (Gentamicin 120mg and Cefuroxime 1.5gm) are given just prior to injection unless contra-indicated.
The injection will be administered under general anaesthetic.

Surgery, Removal of prostate during radical cystoprostatectomy or radical prostatectomy surgery
Post-procedure care: The patient is discharged home once he has recovered from his major surgery as per standard of care. A contact number is given to the patient to call if any problems are encountered.

Intervention Type
Other

Phase
Not Applicable

Primary outcome measure
Rate of serious and other adverse events; Timepoint(s): For the duration the patient is in the study

Secondary outcome measures
1. Anatomical distribution of magnetic nanoparticles compared with injection site in prostate; Timepoint(s): On removal of the prostate
2. Percentage microsphere retention using Perl staining on whole-mount histology; Timepoint (s): At removal of the prostate

Overall study start date
04/12/2013

Completion date
03/12/2014

Eligibility

Key inclusion criteria
1. Men undergoing:
1.1. Radical cystoprostatectomy for bladder cancer, or
1.2. Radical prostatectomy for prostate cancer
2. Men able to give informed consent

Participant type(s)
Patient

Age group
Adult

Sex
Male

Target number of participants
Planned Sample Size: 18; UK Sample Size: 18

Key exclusion criteria
1. Have taken any form of hormones (except 5alpha
reductase inhibitors) within the last 6 months
2. Unable to have MRI scan or CT scan, or in whom artefact would reduce scan quality
3. Unable to have general or regional anaesthesia
4. Men on immunosuppression or predefined immunosuppressed state
5. Men with a coagulopathy predisposing to bleeding to clot formation
6. Men with an inherited or acquired condition limiting metabolism of iron
7. Unable to give informed consent

Date of first enrolment
04/12/2013

Date of final enrolment
03/12/2014

Locations

Countries of recruitment
England

United Kingdom

Study participating centre

University College London
London
United Kingdom
W1W 7EJ

Sponsor information

Organisation
University College London (UK)

Sponsor details
Gower Street
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Sponsor type
University/education

ROR
https://ror.org/02jx3x895

Funder(s)

Funder type
Government

Funder Name
NIHR (UK) - Central Commissioning Facility

Results and Publications

Publication and dissemination plan
Not provided at time of registration

Intention to publish date
09/08/2019

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?
HRA research summary			28/06/2023	No	No