ISRCTN96083641 https://doi.org/10.1186/ISRCTN96083641

# 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
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# 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 |