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The effect of magnetic resonance imaging localisation of prostate cancer on transrectal ultrasound biopsy detection rate

Submission date 30/09/2005	**Recruitment status** No longer recruiting	[_] Prospectively registered [_] Protocol [_] Statistical analysis plan [_] Results [_] Individual participant data [_] Record updated in last year
Registration date 30/09/2005	**Overall study status** Completed	
Last Edited 05/02/2018	**Condition category** Cancer	

Plain English summary of protocol
Not provided at time of registration

Contact information

Type(s)
Scientific

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Additional identifiers

EudraCT/CTIS number

IRAS number

ClinicalTrials.gov number

Secondary identifying numbers
N0436146607

Study information

Scientific Title
The effect of magnetic resonance imaging localisation of prostate cancer on transrectal ultrasound biopsy detection rate

Study objectives
To investigate whether localisation information from magnetic resonance imaging (MRI) can be used to improve the accuracy of trans-rectal ultrasound (TRUS) biopsy and thereby improve the detection rate of prostate cancer.

Ethics approval required
Old ethics approval format

Ethics approval(s)
Not provided at time of registration

Study design
Randomised controlled trial

Primary study design
Interventional

Secondary study design
Randomised controlled trial

Study setting(s)
Hospital

Study type(s)
Diagnostic

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
Prostate cancer

Interventions
Randomised controlled trial

Intervention Type
Other

Phase
Not Specified

Primary outcome measure
Percentage of patients with at least one positive biopsy in each cohort

Secondary outcome measures
Not provided at time of registration

Overall study start date
09/02/2004

Completion date
01/08/2005

Eligibility

Key inclusion criteria
All patients who are to have a transrectal ultrasound (TRUS) biopsy (on a Thursday) to confirm prostate cancer, with an intermediate PSA level (10-19 ng/ml), will be eligible for entry to the study. On average 8 patients undergo TRUS biopsy at Cookridge Hospital per week (divided between Tuesday and Thursday morning sessions). One MRI slot per week (Thursday morning) will be available for the study. All consenting patients will be randomised and one selected for the MRI cohort and all others will form the non-MRI cohort. Assuming at least 2 patients are recruited a week (50%) recruitment rate) the two cohorts (61 patients in each) will be recruited in 61 weeks.

Participant type(s)
Patient

Age group
Adult

Sex
Male

Target number of participants
122

Key exclusion criteria
1. Unwilling/unable to give informed consent
2. Significant claustrophobia
3. Contra indications to MRI: pacemaker, aneurysm clips, metallic foreign bodies in the eye

Date of first enrolment
09/02/2004

Date of final enrolment
01/08/2005

Locations

Countries of recruitment
England

United Kingdom

Study participating centre
Leeds General Infirmary
Leeds
United Kingdom
LS1 3EX

Sponsor information

Organisation
Department of Health

Sponsor details
Richmond House
79 Whitehall
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SW1A 2NL
+44 (0)20 7307 2622
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Sponsor type
Government

Website
http://www.dh.gov.uk/Home/fs/en

Funder(s)

Funder type
Government

Funder Name
Leeds Teaching Hospitals NHS Trust (UK)

Funder Name

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