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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

Contact name
Miss S Jervis

Contact details
Medical Physics
Wellcome Wing
Leeds General Infirmary
Great George Street
Leeds
United Kingdom
LS1 3EX
+44 (0)113 392 6495
r&d@leedsth.nhs.uk

Additional identifiers

Protocol serial number
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

Primary study design
Interventional

Study design
Randomised controlled trial

Study type(s)
Diagnostic

Health condition(s) or problem(s) studied
Prostate cancer

Interventions
Randomised controlled trial

Intervention Type
Other

Phase
Not Specified

Primary outcome(s)
Percentage of patients with at least one positive biopsy in each cohort

Key secondary outcome(s)
Not provided at time of registration

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

Healthy volunteers allowed
No

Age group
Adult

Sex
Male

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
United Kingdom

England

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

Sponsor information

Organisation
Department of Health

Funder(s)

Funder type
Government

Funder Name
Leeds Teaching Hospitals NHS Trust (UK)

Funder Name
NHS R&D Support Funding

Results and Publications

Individual participant data (IPD) sharing plan

IPD sharing plan summary
Not provided at time of registration