

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	<input type="checkbox"/> Prospectively registered
		<input type="checkbox"/> Protocol
Registration date 30/09/2005	Overall study status Completed	<input type="checkbox"/> Statistical analysis plan
		<input type="checkbox"/> Results
Last Edited 05/02/2018	Condition category Cancer	<input type="checkbox"/> Individual participant data
		<input type="checkbox"/> Record updated in last year

Plain English summary of protocol
Not provided at time of registration

Contact information

Type(s)
Scientific

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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

Study design

Randomised controlled trial

Primary study design

Interventional

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