

Advanced imaging of prostate with 4-D ultrasound in suspected cases of prostate cancer: a randomised prospective study

Submission date 12/09/2003	Recruitment status Stopped	☐ Prospectively registered ☐ Protocol
Registration date 12/09/2003	Overall study status Stopped	☐ Statistical analysis plan ☐ Results
Last Edited 23/10/2012	Condition category Cancer	☐ Individual participant data ☐ 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
N0024108495

Study information

Scientific Title

Study objectives

The use of real time 3-D (4-D ultrasound) guided transrectal biopsy of prostate improves sensitivity and specificity in identifying potential malignant foci in prostate gland compared to conventional 2-D ultrasonography.

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)

Not Specified

Health condition(s) or problem(s) studied

Cancer: Prostate

Interventions

- 1.. 4-D ultrasound
2. Standard care

July 2008: trial not started.

Intervention Type

Other

Phase

Not Specified

Primary outcome(s)

1. Total PSA prostate volume
2. Volume of the tumour
3. PSA Density: PSA X volume
4. Histology of the cores: Gleason grading
5. Doppler findings: Pulsatility index, peak systolic volume, resistance index, flow velocity

Key secondary outcome(s)

Not provided at time of registration

Completion date

31/01/2004

Reason abandoned (if study stopped)

Not started because of lack of funding

Eligibility

Key inclusion criteria

1. Patients with suspected carcinoma of the prostate, ie raised prostate specific antigen (PSA)
2. Age group 45-70 years

Participant type(s)

Patient

Healthy volunteers allowed

No

Age group

Adult

Sex

Male

Key exclusion criteria

Not provided at time of registration

Date of first enrolment

01/09/2002

Date of final enrolment

31/01/2004

Locations

Countries of recruitment

United Kingdom

England

Study participating centre

Department of Urology

London

United Kingdom

E9 6SR

Sponsor information

Organisation

Department of Health (UK)

Funder(s)

Funder type

Government

Funder Name

Homerton University Hospital NHS Trust (UK)

Results and Publications

Individual participant data (IPD) sharing plan

IPD sharing plan summary

Not provided at time of registration