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

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| **Submission date**<br>12/09/2003 | **Recruitment status**<br>Stopped | [ ] Prospectively registered<br>[ ] Protocol<br>[ ] Statistical analysis plan<br>[ ] Results<br>[ ] Individual participant data<br>[ ] Record updated in last year |
| **Registration date**<br>12/09/2003 | **Overall study status**<br>Stopped | |
| **Last Edited**<br>23/10/2012 | **Condition category**<br>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**

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

### Study design
Randomised controlled trial

### Primary study design
Interventional

### Secondary study design
Randomised controlled trial

### Study setting(s)
Not specified

### Study type(s)
Not Specified

### Participant information sheet

### 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 measure
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

### Secondary outcome measures
Not provided at time of registration

### Overall study start date
01/09/2002

### 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

### Age group
Adult

### Sex
Male

### Target number of participants
Total 60 patients, 30 patients in 2-D group, 30 patients in 4-D group

### 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

England

United Kingdom

**Study participating centre**
**Department of Urology**
London
United Kingdom
E9 6SR

# Sponsor information

**Organisation**
Department of Health (UK)

**Sponsor details**
Richmond House
79 Whitehall
London
United Kingdom
SW1A 2NL

**Sponsor type**
Government

**Website**
http://www.doh.gov.uk

# Funder(s)

**Funder type**
Government

**Funder Name**
Homerton University Hospital NHS Trust (UK)

# 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