

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

<b>Submission date</b> 12/09/2003	<b>Recruitment status</b> Stopped	<input type="checkbox"/> Prospectively registered <input type="checkbox"/> Protocol
<b>Registration date</b> 12/09/2003	<b>Overall study status</b> Stopped	<input type="checkbox"/> Statistical analysis plan <input type="checkbox"/> Results
<b>Last Edited</b> 23/10/2012	<b>Condition category</b> Cancer	<input type="checkbox"/> Individual participant data <input type="checkbox"/> Record updated in last year

## Plain English Summary

Not provided at time of registration

## Contact information

### Type(s)

Scientific

### Contact name

Mr Vinod Nargund

### Contact details

Department of Urology  
Homerton University Hospital NHS Trust  
Homerton Row  
London  
United Kingdom  
E9 6SR  
+44 020 8510 7522  
vinod.nargund@homerton.nhs.uk

## Additional identifiers

EudraCT/CTIS number

IRAS number

ClinicalTrials.gov number

Secondary identifying numbers

N0024108495

## Study information

### Scientific Title

#### Study hypothesis

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

#### Condition

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

**Overall study end date**

31/01/2004

**Reason abandoned (if study stopped)**

Not started because of lack of funding

## Eligibility

**Participant 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

**Participant exclusion criteria**

Not provided at time of registration

**Recruitment start date**

01/09/2002

**Recruitment end date**

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