The effect of needle thickness on the diagnosis of prostate cancer

Submission date	Recruitment status	Prospectively registered
28/09/2007	No longer recruiting	Protocol
Registration date	Overall study status	Statistical analysis plan
28/09/2007	Completed	Results
Last Edited	Condition category	Individual participant data
12/10/2017	Cancer	Record updated in last year

Plain English summary of protocol

Not provided at time of registration

Contact information

Type(s)

Scientific

Contact name

Mr Rahul Mistry

Contact details

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Additional identifiers

EudraCT/CTIS number

IRAS number

ClinicalTrials.gov number

Secondary identifying numbers

N0280190231

Study information

Scientific Title

The effect of needle thickness on the diagnosis of prostate cancer

Study objectives

- 1. To determine if using smaller needles to biopsy the prostate provides tissue that is equally accurate for histopathological examination.
- 2. To analyse the post-operative pain perception following local anaesthetic infiltration or sedation prostrate biopsies.
- 3. To determine if there are any post-operative complications or erectile dysfunction following prostrate biopsies.

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)

Hospital

Study type(s)

Diagnostic

Participant information sheet

Not available in web format, please use the contact details to request a patient information sheet

Health condition(s) or problem(s) studied

Cancer: Prostate

Interventions

Double blind binary randomization to either large needle TRUS biopsy or small needle TRUS biopsy.

Intervention Type

Other

Phase

Not Specified

Primary outcome measure

- 1. Pre-op erectile dysfunction questionnaire
- 2. Post-op pain evaluation
- 3. Complication & ED questionnaire
- 4. Prostate histopathology

Secondary outcome measures

Not provided at time of registration

Overall study start date

01/12/2006

Completion date

01/12/2007

Eligibility

Key inclusion criteria

75-100 consecutive men undergoing TRUS prostate biopsies for investigation into a raised PSA level &/or an abnormal digital rectal examination (DRE)

Participant type(s)

Patient

Age group

Adult

Sex

Male

Target number of participants

100

Key exclusion criteria

Does not meet inclusion criteria

Date of first enrolment

01/12/2006

Date of final enrolment

01/12/2007

Locations

Countries of recruitment

England

United Kingdom

Study participating centre Clatterbridge Hospital Wirral

United Kingdom CH63 4JY

Sponsor information

Organisation

Record Provided by the NHSTCT Register - 2007 Update - Department of Health

Sponsor details

The Department of Health, Richmond House, 79 Whitehall London United Kingdom SW1A 2NL +44 (0)20 7307 2622 dhmail@doh.gsi.org.uk

Sponsor type

Government

Website

http://www.dh.gov.uk/Home/fs/en

Funder(s)

Funder type

Government

Funder Name

Wirral Hospitals NHS Trust

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 summaryNot provided at time of registration