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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

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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
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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 summary
Not provided at time of registration