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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

Contact name
Mr Rahul Mistry

Contact details
Urology Dept, Ward M2
Clatterbridge Hospital
Clatterbridge Road
Bebington
Wirral
United Kingdom
CH63 4JY
+44 (0)7967339014
rahulmistry1@hotmail.com

Additional identifiers

Protocol serial number
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

Study type(s)
Diagnostic

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

Key secondary outcome(s))
Not provided at time of registration

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

Healthy volunteers allowed
No

Age group
Adult

Sex
Male

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
United Kingdom

England

Study participating centre
Clatterbridge Hospital
Wirral
United Kingdom
CH63 4JY

Sponsor information

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

Funder(s)

Funder type
Government

Funder Name
Wirral Hospitals NHS Trust

Results and Publications

Individual participant data (IPD) sharing plan

IPD sharing plan summary
Not provided at time of registration