

The effect of needle thickness on the diagnosis of prostate cancer

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| Submission date 28/09/2007 | Recruitment status No longer recruiting | <input type="checkbox"/> Prospectively registered |
| | | <input type="checkbox"/> Protocol |
| Registration date 28/09/2007 | Overall study status Completed | <input type="checkbox"/> Statistical analysis plan |
| | | <input type="checkbox"/> Results |
| Last Edited 12/10/2017 | Condition category Cancer | <input type="checkbox"/> Individual participant data |
| | | <input type="checkbox"/> 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

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 prostate biopsies.
3. To determine if there are any post-operative complications or erectile dysfunction following prostate 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