# 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

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

# **Study outputs**

Output type Details Date created Date added Peer reviewed? Patient-facing?

Participant information sheet 11/11/2025 No Yes