

# Study of topical glyceryl trinitrate and tolerance of transrectal ultrasound-guided prostate biopsy (TRUS biopsy).

<b>Submission date</b> 30/09/2004	<b>Recruitment status</b> No longer recruiting	<input type="checkbox"/> Prospectively registered
		<input type="checkbox"/> Protocol
<b>Registration date</b> 30/09/2004	<b>Overall study status</b> Completed	<input type="checkbox"/> Statistical analysis plan
		<input checked="" type="checkbox"/> Results
<b>Last Edited</b> 01/10/2012	<b>Condition category</b> Cancer	<input type="checkbox"/> Individual participant data

**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**  
N0176127662

## Study information

**Scientific Title**

**Study objectives**

TRUS biopsy is the technique of choice for the diagnosis of carcinoma of the prostate (CaP), particularly for early stage tumours. The number of procedures is likely to escalate in the future. The procedure is performed in an outpatient setting without sedation, and without topical analgesia. However, many patients regard the uncomfortable nature of anal distension on the introduction of the rectal ultrasound probe as the most distressing feature of the procedure, and we hope that this can be alleviated with topical GTN (topical glyceryl trinitrate) paste.

Patients will either complete the study by undergoing biopsy with GTN or control paste or withdraw and require inhaled nitrous oxide/general anaesthetic. We hope to recruit 100 patients.

**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)**

Not Specified

**Health condition(s) or problem(s) studied**

Cancer: Prostate

**Interventions**

Glyceryl trinitrate (GTN) or control paste

**Intervention Type**

Drug

**Phase**

Not Specified

**Drug/device/biological/vaccine name(s)**

topical glyceryl trinitrate

**Primary outcome(s)**

Not provided at time of registration

**Key secondary outcome(s)**

Not provided at time of registration

**Completion date**

01/05/2004

## Eligibility

### Key inclusion criteria

Not provided at time of registration

### Participant type(s)

Patient

### Healthy volunteers allowed

No

### Age group

Not Specified

### Sex

Not Specified

### Key exclusion criteria

Not provided at time of registration

### Date of first enrolment

01/05/2003

### Date of final enrolment

01/05/2004

## Locations

### Countries of recruitment

United Kingdom

England

### Study participating centre

Department of Urology

Oxford

United Kingdom

OX3 7LJ

## Sponsor information

### Organisation

Department of Health

## Funder(s)

### Funder type

Government

### Funder Name

Oxford Radcliffe Hospitals NHS Trust (UK)

## 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?
<a href="#">Results article</a>	results	01/02/2005		Yes	No