

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

Submission date 30/09/2004	Recruitment status No longer recruiting	☐ Prospectively registered ☐ Protocol
Registration date 30/09/2004	Overall study status Completed	☐ Statistical analysis plan ☒ Results
Last Edited 01/10/2012	Condition category Cancer	☐ Individual participant data

Plain English summary of protocol
Not provided at time of registration

Contact information

Type(s)
Scientific

Contact name
Mr Simon F Brewster

Contact details
Department of Urology
Churchill Hospital
Churchill Drive
Headington
Oxford
United Kingdom
OX3 7LJ
+44 (0)1865 225717

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

Primary study design

Interventional

Study design

Randomised controlled trial

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?
Results article	results	01/02/2005		Yes	No