ISRCTN49593371 https://doi.org/10.1186/ISRCTN49593371

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 [_] Statistical analysis plan [X] Results [_] Individual participant data
Registration date 30/09/2004	**Overall study status** Completed	
Last Edited 01/10/2012	**Condition category** Cancer	

Plain English summary of protocol
Not provided at time of registration

Contact information

Type(s)
Scientific

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Additional identifiers

EudraCT/CTIS number

IRAS number

ClinicalTrials.gov number

Secondary identifying numbers

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

Secondary study design
Randomised controlled trial

Study setting(s)
Not specified

Study type(s)
Not Specified

Participant information sheet
Not available in web format, please use the contact details below to request a patient information sheet

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 measure
Not provided at time of registration

Secondary outcome measures
Not provided at time of registration

Overall study start date
01/05/2003

Completion date
01/05/2004

Eligibility

Key inclusion criteria
Not provided at time of registration

Participant type(s)
Patient

Age group
Not Specified

Sex
Not Specified

Target number of participants
100

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

England

United Kingdom

Study participating centre
Department of Urology
Oxford
United Kingdom
OX3 7LJ

Sponsor information

Organisation
Department of Health

Sponsor details
Richmond House
79 Whitehall
London
United Kingdom
SW1A 2NL

Sponsor type
Government

Website
http://www.dh.gov.uk/Home/fs/en

Funder(s)

Funder type
Government

Funder Name
Oxford Radcliffe Hospitals NHS Trust (UK)

Results and Publications

Publication and dissemination plan
Not provided at time of registration

Intention to publish date

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