

A prospective, randomised, double-blind placebo-controlled trial of effects of glyceryl trinitrate ointment on the pain experiences during transdermal ultrasound guided biopsy of the prostate

Submission date 12/09/2003	Recruitment status No longer recruiting	<input type="checkbox"/> Prospectively registered
Registration date 12/09/2003	Overall study status Completed	<input type="checkbox"/> Protocol
Last Edited 31/03/2020	Condition category Urological and Genital Diseases	<input type="checkbox"/> Statistical analysis plan
		<input type="checkbox"/> Results
		<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
N0040122630

Study information

Scientific Title

A prospective, randomised, double-blind placebo-controlled trial of effects of glyceryl trinitrate ointment on the pain experiences during transdermal ultrasound guided biopsy of the prostate

Study objectives

To test the hypothesis: Topical 0.2% GTN ointment reduced the discomfort or pain experiences during transrectal ultrasound guided biopsy of the prostate. Results will be submitted for presentation to a national/international urology meeting.

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)

Treatment

Health condition(s) or problem(s) studied

Urological and Genital Diseases: Prostate biopsy

Interventions

Glyceryl trinitrate ointment vs placebo

Intervention Type

Other

Phase

Not Specified

Primary outcome(s)

Not provided at time of registration

Key secondary outcome(s)

Not provided at time of registration

Completion date

01/09/2003

Eligibility

Key inclusion criteria

After logistical considerations, we propose to aim for 50 patients in each group so that we might detect a difference in pain score 1/10 with a power of 90% and the aforementioned assumptions. It should be possible to complete this study in less than 6 months.

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

01/03/2003

Date of final enrolment

01/09/2003

Locations**Countries of recruitment**

United Kingdom

England

Study participating centre

Bedford Hospital NHS Trust

Bedford

United Kingdom

MK42 9DJ

Sponsor information**Organisation**

Department of Health (UK)

Funder(s)

Funder type

Hospital/treatment centre

Funder Name

Bedford Hospital NHS Trust (UK)

Results and Publications

Individual participant data (IPD) sharing plan

IPD sharing plan summary

Not provided at time of registration