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	Recruitment status	Prospectively registered
12/09/2003	No longer recruiting	☐ Protocol
Registration date	Overall study status	Statistical analysis plan
12/09/2003	Completed	Results
Last Edited	Condition category	Individual participant data
31/03/2020	Urological and Genital Diseases	Record updated in last year

Plain English summary of protocol

Not provided at time of registration

Contact information

Type(s)

Scientific

Contact name

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Contact details

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Additional identifiers

EudraCT/CTIS number

IRAS number

ClinicalTrials.gov number

Secondary identifying numbers

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

Secondary study design

Randomised controlled trial

Study setting(s)

Hospital

Study type(s)

Treatment

Participant information sheet

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 measure

Not provided at time of registration

Secondary outcome measures

Not provided at time of registration

Overall study start date

01/03/2003

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

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

01/03/2003

Date of final enrolment

01/09/2003

Locations

Countries of recruitment

England

United Kingdom

Study participating centre

Bedford Hospital NHS Trust

Bedford United Kingdom MK42 9DJ

Sponsor information

Organisation

Department of Health (UK)

Sponsor details

Richmond House 79 Whitehall London United Kingdom SW1A 2NL

Sponsor type

Government

Website

http://www.doh.gov.uk

Funder(s)

Funder type

Hospital/treatment centre

Funder Name

Bedford Hospital 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