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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

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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