

A randomised placebo-controlled study of Tamsulosin, Voltarol and the combination in types IIIa and IIIb prostatitis using the newly developed and validated National Institutes of Health (NIH) symptom score

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 03/01/2020	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

EudraCT/CTIS number

IRAS number

ClinicalTrials.gov number

Secondary identifying numbers

N0544074138

Study information

Scientific Title

-

Study objectives

Alpha blockers and Voltarol in treating chronic prostatitis

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)

Treatment

Participant information sheet

Health condition(s) or problem(s) studied

Urological and Genital Diseases: Prostatitis

Interventions

The study is a randomised controlled trial using four arms in the treatment of chronic pelvic pain syndrome in men:

1. Placebo only
2. Tamsulosin
3. Voltarol
4. Tamsulosin and Voltarol

The study will require the usual investigations for chronic prostatitis, and then a 6-week randomisation period in one of the four arms of treatment, taking a total of four tablets a day.

The main outcome measure will be a reduction in the National Institute of Health Chronic Prostatitis Symptom Index (NIHCPSI), which is a newly produced and validated symptom score for assessing men with this condition.

Intervention Type

Drug

Phase

Not Applicable

Drug/device/biological/vaccine name(s)

Tamsulosin, Voltarol

Primary outcome measure

Not provided at time of registration

Secondary outcome measures

Not provided at time of registration

Overall study start date

04/05/2000

Completion date

03/11/2003

Eligibility**Key inclusion criteria**

60 patients aged between 30 and 50

Participant type(s)

Patient

Age group

Adult

Sex

Male

Target number of participants

60

Key exclusion criteria

Not provided at time of registration

Date of first enrolment

04/05/2000

Date of final enrolment

03/11/2003

Locations

Countries of recruitment

England

United Kingdom

Study participating centre

Box No 43

Cambridge

United Kingdom

CB2 2QQ

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

Government

Funder Name

Cambridge Consortium - Addenbrooke's (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