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	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
03/01/2020	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

Dr Richard Batstone

Contact details

Box No 43
Department of Urology
Addenbrooke's NHS Trust
Cambridge
United Kingdom
CB2 2QQ
+44 (0)1223 216070
hf@cct.com

Additional identifiers

Protocol serial number

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

Study type(s)

Treatment

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(s)

Not provided at time of registration

Key secondary outcome(s))

Not provided at time of registration

Completion date

03/11/2003

Eligibility

Key inclusion criteria

60 patients aged between 30 and 50

Participant type(s)

Patient

Healthy volunteers allowed

No

Age group

Adult

Sex

Male

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

United Kingdom

England

Study participating centre

Box No 43

Cambridge United Kingdom CB2 2QQ

Sponsor information

Organisation

Department of Health (UK)

Funder(s)

Funder type

Government

Funder Name

Cambridge Consortium - Addenbrooke's (UK)

Results and Publications

Individual participant data (IPD) sharing plan

IPD sharing plan summary

Not provided at time of registration