ISRCTN46815629 https://doi.org/10.1186/ISRCTN46815629

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

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