ISRCTN85291415 https://doi.org/10.1186/ISRCTN85291415

A multicentre, randomised clinical trial to evaluate the efficacy of oral ciprofloxacin, oral tamsulosin, and the combination of oral ciprofloxacin and oral tamsulosin for the treatment of Chronic Prostatitis/Chronic Pelvic Pain Syndrome

Submission date
30/06/2004

Registration date
11/11/2004

Last Edited
25/08/2009

Recruitment status
No longer recruiting

Overall study status
Completed

Condition category
Urological and Genital Diseases

[_] Prospectively registered
[_] Protocol
[_] Statistical analysis plan
[X] Results
[_] Individual participant data

Plain English summary of protocol
Not provided at time of registration

Contact information

Type(s)
Scientific

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Additional identifiers

Protocol serial number
N/A

Study information

Scientific Title

Study objectives
Not provided at time of registration

Ethics approval required
Old ethics approval format

Ethics approval(s)
Not provided at time of registration

Study design
Multicentre randomised double blind placebo controlled 2x2 factorial trial

Primary study design
Interventional

Study type(s)
Treatment

Health condition(s) or problem(s) studied
Chronic Prostatitis (CP)/Chronic Pelvic Pain Syndrome (CPPS)

Interventions
A 2x2 factorial design assessing four interventions: ciprofloxacin alone, tamsulosin alone, the combination of ciprofloxacin and tamsulosin, and placebo. All treatments were provided for six weeks.

Please note that as of 25/08/09 the start and end dates of this trial have been updated. The initial dates, 01/04/2002 to 30/04/2004, were generated at the time of registration.

Intervention Type
Drug

Phase
Not Specified

Drug/device/biological/vaccine name(s)
Ciprofloxacin, tamsulosin

Primary outcome(s)
Not provided at time of registration

Key secondary outcome(s))
Not provided at time of registration

Completion date

30/09/2002

Eligibility

Key inclusion criteria
Approximately 184 participants, 46 per arm, were treated and followed for a total of 12 weeks. These participants were male, had symptoms of discomfort or pain in the pelvic region for at least a 3 month period within the last 6 months, and had a overall score of equal to or greater than 15 out of 43 points on the National Institutes of Health Chronic Prostatitis Symptom Index (NIH-CPSI) Total Score.

Participant type(s)
Patient

Healthy volunteers allowed
No

Age group
Adult

Lower age limit
18 years

Sex
Male

Key exclusion criteria
Does not match inclusion criteria

Date of first enrolment
01/07/2001

Date of final enrolment
30/09/2002

Locations

Countries of recruitment
United States of America

Study participating centre
University of Pennsylvania School of Medicine
Philadelphia, PA
United States of America
19104-6021

Sponsor information

Organisation
National Institute of Diabetes and Digestive and Kidney Diseases, National Institutes of Health (NIDDK, NIH) (USA)

ROR
https://ror.org/00adh9b73

Funder(s)

Funder type
Government

Funder Name
National Institutes of Health (NIH) (USA) - cooperative agreements U01 DK53572, U01 DK53730, U01 DK53736, U01 DK53734, U01 DK53732, U01 DK53746, and U01 DK53738.

Funder Name
Boehringer Ingelheim (USA) - provided tamsulosin and matching placebo

Funder Name
Bayer Corporation (USA) - provided ciprofloxacin and matching placebo.

Results and Publications

Individual participant data (IPD) sharing plan

IPD sharing plan summary
Not provided at time of registration

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
Results article	results	19/10/2004		Yes	No