

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	Recruitment status No longer recruiting	<input type="checkbox"/> Prospectively registered
Registration date 11/11/2004	Overall study status Completed	<input type="checkbox"/> Protocol
Last Edited 25/08/2009	Condition category Urological and Genital Diseases	<input type="checkbox"/> Statistical analysis plan
		<input checked="" type="checkbox"/> Results
		<input type="checkbox"/> 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

EudraCT/CTIS number

IRAS number

ClinicalTrials.gov number

Secondary identifying numbers

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

Secondary study design

Randomised controlled trial

Study setting(s)

Hospital

Study type(s)

Treatment

Participant information sheet

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 measure

Not provided at time of registration

Secondary outcome measures

Not provided at time of registration

Overall study start date

01/07/2001

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

Age group

Adult

Lower age limit

18 Years

Sex

Male

Target number of participants

184 (196 final [added 25/08/09])

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)

Sponsor details

Dr John W. Kusek

2 Democracy Plaza

Room 617

6707 Democracy Boulevard

Bethesda, MD

United States of America

20892-5458

Sponsor type

Research organisation

Website

<http://www.niddk.nih.gov>

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

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

Study outputs

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