

Clinical Trial Protocol

Iranian Registry of Clinical Trials

28 Jul 2026

Assessment the effect of focused extracorporeal shockwave therapy in pain management, erectile dysfunction and urinary symptoms in patients suffering from chronic pelvic pain syndrome - a randomized clinical trial

Protocol summary

Summary

In this single center phase III clinical trial, 34 patients with diagnosis of chronic prostatitis/chronic pelvic pain syndrome (according to history and physical examination and urodynamic study) who are referred to Shohada-e-Tajrish urology clinic are enrolled. They are divided into two groups: the first group numbered 17 patients, who are treated with a combination of an a-blocker, an anti-inflammatory agent, a muscle relaxant and a short course of antibiotic treatment in combination with 4 sessions of perineal focused extracorporeal shockwave therapy (ESWT); the second group consist of 17 patients who receive a combination of sham-ESWT and the fore-mentioned triple therapy and short course of antibiotic. Patients and data analyzer are blind to data. Both groups are evaluated with NIH-CPSI, IPSS and IIEF5 questionnaires and uroflowmetry, at the beginning, 1 month and 3 months after treatment, and the results will be compared between both groups.

General information

Acronym

IRCT registration information

IRCT registration number: **IRCT2017082635911N1**

Registration date: **2017-11-17, 1396/08/26**

Registration timing: **registered_while_recruiting**

Last update:

Update count: **0**

Registration date

2017-11-17, 1396/08/26

Registrant information

Name

Farzad Allameh

Name of organization / entity

Shahid Beheshti University of Medical Sciences

Country

Iran (Islamic Republic of)

Phone

+98 21 2273 6386

Email address

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Recruitment status

Recruitment complete

Funding source

Shahid Beheshti University of Medical Sciences

Expected recruitment start date

2017-09-23, 1396/07/01

Expected recruitment end date

2018-01-05, 1396/10/15

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Assessment the effect of focused extracorporeal shockwave therapy in pain management, erectile dysfunction and urinary symptoms in patients suffering from chronic pelvic pain syndrome - a randomized clinical trial

Public title

Shock-wave therapy in men with pelvic pain

Purpose

Treatment

Inclusion/Exclusion criteria

Inclusion criteria: >18 years old; definite diagnosis of CPPS; Symptomatic for at least 3 months; no treatment before; sign the informed consent Exclusion criteria: acute or chronic bacterial prostatitis; UTI in 1 recent

year; history of prostate cancer or PSA>4; coagulation problems; history of hematuria, urethral stricture, urologic cancers, urolithiasis, neurogenic bladder, STDs, colorectal problems, inguinal hernia and varicocele; drug addiction

Age

From **18 years** old

Gender

Male

Phase

3

Groups that have been masked

No information

Sample size

Target sample size: **34**

Randomization (investigator's opinion)

Randomized

Randomization description

Blinding (investigator's opinion)

Double blinded

Blinding description

Placebo

Used

Assignment

Parallel

Other design features

Randomization method: closed envelopes

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee

Ethic committee of Shahid Beheshti University of Medical Sciences - School of Medicine

Street address

Arabi street, Daneshjoo Boulevard, Velenjak

City

Tehran

Postal code

Approval date

2017-05-30, 1396/03/09

Ethics committee reference number

IR.SBMU.MSP.REC.1396.158

Health conditions studied

1

Description of health condition studied

Chronic Pelvic Pain Syndrome (Chronic Prostatitis)

ICD-10 code

N41.1

ICD-10 code description

Chronic prostatitis

Primary outcomes

1

Description

Pain

Timepoint

before, 1 and 3 months after procedure

Method of measurement

Visual Analog Scale Questionnaire

2

Description

Qmax

Timepoint

before, 1 and 3 months after procedure

Method of measurement

Uroflowmetry

3

Description

Erectile Dysfunction

Timepoint

before, 1 and 3 months after procedure

Method of measurement

International Index of Erectile Function 5 Questionnaire

4

Description

Symptoms Severity

Timepoint

before, 1 and 3 months after procedure

Method of measurement

National Institute of Health Chronic Prostatitis Index Questionnaire

5

Description

Lower urinary Tract Symptoms

Timepoint

before, 1 and 3 months after procedure

Method of measurement

International Prostate Symptom Score Questionnaire

Secondary outcomes

1

Description

Hematuria

Timepoint

1 and 3 months after procedure

Method of measurement

Inreview

2

Description

Hemospermia

Timepoint

1 and 3 months after procedure

Method of measurement

Interview

3**Description**

Post void residue

Timepoint

before, 1 and 3 months after

Method of measurement

uroflowmetry

Intervention groups**1****Description**

Intervention : Cap tamsolusin (Abidi Co) 0.4 mg qhs 3 months Tab Alfex XL (Abidi Co) 100 mg Daily for 3 months Tab Baclofen (Abidi Co) 10 mg BD for 3 months Tab ofloxacin (Abidi Co) 300 mg BD for 2 weeks 4 sessions of perineal focused ESWT (STORZ Co) Weekly

Category

Treatment - Drugs

2**Description**

Control : Cap Tamsolusin (Abidi Co) 0.4 mg qhs for 3 months Tab Alfex XL (Abidi Co) 100 mg Daily for 3 months Tab Baclofen (Abidi Co) 10 mg BD for 3 months Tab Ofloxacin (Abidi Co) 300 mg BD for 2 weeks 4 sessions of perineal Sham ESWT (STORZ Co) Weekly

Category

Placebo

Recruitment centers**1****Recruitment center****Name of recruitment center**

Shohada-e-Tajrish Hospital

Full name of responsible person

Farzad Allameh

Street address

Tajrish Square

City

Tehran

Sponsors / Funding sources**1****Sponsor****Name of organization / entity**

Vice chancellor for research, Shahid Beheshti University of Medical Sciences

Full name of responsible person

Ms Mehrnoush Moinefar

Street address

Shohada-e-Tajrish Hospital, Tajrish Square

City

Tehran

Grant name**Grant code / Reference number**

-

Is the source of funding the same sponsor organization/entity?

Yes

Title of funding source

Vice chancellor for research, Shahid Beheshti University of Medical Sciences

Proportion provided by this source

100

Public or private sector

empty

Domestic or foreign origin

empty

Category of foreign source of funding

empty

Country of origin**Type of organization providing the funding**

empty

Person responsible for general inquiries**Contact****Name of organization / entity**

Shahid Beheshti University of Medical Sciences

Full name of responsible person

Farzad Allameh

Position

Assistant Professor

Other areas of specialty/work**Street address**

Shohada-e-Tajrish Hospital, Tajrish Square

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farzadallame@gmail.com

Web page address**Person responsible for scientific inquiries****Contact****Name of organization / entity**

Shahid Beheshti University of Medical Sciences

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Position

MD-MPH Urologist

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Sharing plan

Deidentified Individual Participant Data Set (IPD)

empty

Study Protocol

empty

Statistical Analysis Plan

empty

Informed Consent Form

empty

Clinical Study Report

empty

Analytic Code

empty

Data Dictionary

empty