

Clinical Trial Protocol

Iranian Registry of Clinical Trials

23 Feb 2026

Effectiveness of pregabalin as an adjuvant therapy for chronic nonbacterial prostatitis

Protocol summary

Summary

Objective: To determine the effectiveness of pregabalin as an adjuvant therapy for chronic nonbacterial prostatitis. Design: A double-blind block randomized clinical trial. Study population: Male patients with chronic nonbacterial prostatitis. Inclusion criteria: 1) Age over 18 years; 2) no prior history of other urinary system disorders such as urinary tract stones, neurogenic bladder, and urinary infections; 3) no history of major underlying diseases such as cirrhosis, renal failure, diabetes, or hypertension; 4) normal levels of urine, fasting blood sugar (FBS), and creatinine; 5) normal results on the first neurological examination of the perineal area, lower limbs, lower limb reflexes, and bulbocavernosus reflex; 6) no use of other medicines; 7) no signs of psychological disorders; 8) confirmed diagnosis of chronic prostatitis; 9) non-sensitivity to anti-epileptic drugs, pregabalin, thiazolidinediones, or other anti-diabetic agents. Exclusion criteria: 1) Unwillingness to continue the study, and 2) major side-effects due to the use of medications. Sample size: 288 cases. Study intervention: Use of terazosin tablets (2 mg) and pregabalin capsules (50 mg) on a daily basis for the first week, followed by the daily use of 100 mg pregabalin capsules for six weeks. Study outcome: Evaluation and comparison of pain, urinary symptoms, quality of life, and side-effects of medications between the intervention and control groups, based on the scoring system introduced by the National Institute of Health-Chronic Prostatitis Symptom Index (NIH-CPSI).

General information

Acronym

IRCT registration information

IRCT registration number: **IRCT2016022225507N2**

Registration date: **2016-03-01, 1394/12/11**

Registration timing: **prospective**

Last update:

Update count: **0**

Registration date

2016-03-01, 1394/12/11

Registrant information

Name

Ali Serous

Name of organization / entity

Arak University of Medical Sciences

Country

Iran (Islamic Republic of)

Phone

+98 51 3841 4499

Email address

m-jiriaie@mscstu.scu.ac.ir

Recruitment status

Recruitment complete

Funding source

Vice Chancellor for Research of Arak University of Medical Sciences

Expected recruitment start date

2016-03-20, 1395/01/01

Expected recruitment end date

2017-03-21, 1396/01/01

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Effectiveness of pregabalin as an adjuvant therapy for chronic nonbacterial prostatitis

Public title

Effectiveness of pregabalin on chronic nonbacterial prostatitis

Purpose

Treatment

Inclusion/Exclusion criteria

Inclusion criteria: 1) Age over 18 years; 2) no prior history of other urinary system disorders such as urinary tract stones, neurogenic bladder, and urinary infections; 3) no history of major underlying diseases such as cirrhosis, renal failure, diabetes, or hypertension; 4) normal levels of urine, fasting blood sugar (FBS), and creatinine; 5) normal results on the first neurological examination of the perineal area, lower limbs, lower limb reflexes, and bulbocavernosus reflex; 6) no use of other medicines; 7) no signs of psychological disorders; 8) confirmed diagnosis of chronic prostatitis; 9) non-sensitivity to anti-epileptic drugs, pregabalin, thiazolidinediones, or other anti-diabetic agents.

Exclusion criteria: 1) Unwillingness to continue the study, and 2) major side-effects due to the use of medications.

Age

From **18 years** old to **139 years** old

Gender

Male

Phase

2

Groups that have been masked

No information

Sample size

Target sample size: **288**

Randomization (investigator's opinion)

Randomized

Randomization description

Blinding (investigator's opinion)

Double blinded

Blinding description

Placebo

Used

Assignment

Parallel

Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee

Ethics Committee of Arak University of Medical Sciences

Street address

Vice Chancellor for Research, Arak University of Medical Sciences, A'lam-Al-Hoda Street, Shahid Shiroodi Street

City

Arak

Postal code

Approval date

2015-01-26, 1393/11/06

Ethics committee reference number

93-174-11

Health conditions studied

1

Description of health condition studied

Chronic nonbacterial prostatitis

ICD-10 code

N41.8

ICD-10 code description

Other inflammatory diseases of prostate

Primary outcomes

1

Description

Rang of pain

Timepoint

6 weeks after therapy

Method of measurement

NIH-CPSI scoring system, Scoring from 0 to 21

Secondary outcomes

1

Description

Urinary symptoms

Timepoint

6 weeks after therapy

Method of measurement

NIH-CPSI scoring system, Scoring from 0 to 10

Intervention groups

1

Description

Control group: Patients with chronic nonbacterial prostatitis use of Terazosin tablets (2 mg) and placebo capsules (50 mg) on a daily basis for the first week, followed by the daily use of 100 mg placebo capsules for six weeks, measurement of pain, and urinary symptoms after therapy.

Category

Treatment - Drugs

2

Description

Intervention group: Patients with chronic nonbacterial prostatitis use of terazosin tablets (2 mg) and pregabalin capsules (50 mg) on a daily basis for the first week, followed by the daily use of 100 mg pregabalin capsules for six weeks., measurement of pain, and urinary symptoms after therapy

Category

Treatment - Drugs

Recruitment centers

1

Recruitment center

Name of recruitment center

Valiasr Hospital

Full name of responsible person

Ali Sirous

Street address

Valiasr Hospital-Perozi Avenue

City

Arak

Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Vice Chancellor for Research of Arak University of Medical Sciences

Full name of responsible person

Ali Asghar Yaghobi

Street address

Vice Chancellor for Research, Arak University of Medical Sciences, A'lam-Al-Hoda Street, Shahid Shiroodi Street

City

Arak

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 of Arak 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

Arak University of Medical Sciences

Full name of responsible person

Ali Sirous

Position

Urologist

Other areas of specialty/work

Street address

Arak University of Medical Sciences, A'lam-Al-Hoda

Street, Shahid Shiroodi Street

City

Arak

Postal code

Phone

+98 86 3313 6058

Fax

Email

m-jiriaie@mscstu.scu.ac.ir

Web page address

Person responsible for scientific inquiries

Contact

Name of organization / entity

Arak University of Medical Sciences

Full name of responsible person

Ali Sirous

Position

Urologist

Other areas of specialty/work

Street address

Arak University of Medical Sciences, A'lam-Al-Hoda Street, Shahid Shiroodi Street

City

Arak

Postal code

Phone

+98 86 3313 6058

Fax

Email

m-jiriaie@mscstu.scu.ac.ir

Web page address

Person responsible for updating data

Contact

Name of organization / entity

Arak University of Medical Sciences

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Arak University of Medical Sciences, A'lam-Al-Hoda Street, Shahid Shiroodi Street

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Fax

Email

m-jiriaie@mscstu.scu.ac.ir

Web page address

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