

# 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-Perazi 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

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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**

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## Person responsible for updating data

### Contact

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**Other areas of specialty/work**

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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*