

Clinical Trial Protocol

Iranian Registry of Clinical Trials

18 Jun 2026

A clinical trial to comparison the effectiveness of melatonin and capsules containing starch (placebo) as an adjuvant therapy to control symptoms of chronic nonbacterial prostatitis patients

Protocol summary

Summary

Objective: To compare the effectiveness of melatonin and capsules containing starch (placebo) as an adjuvant therapy to control symptoms of chronic nonbacterial prostatitis patients. Design: A double-blind block randomized clinical trial. Study population: Male patients with chronic nonbacterial prostatitis. Inclusion criteria: Age over 18 years; no prior history of other urinary system disorders such as urinary tract stones, neurogenic bladder and urinary infections; no history of underlying diseases such as cirrhosis, renal failure, diabetes, or hypertension; normal values of urine, fasting blood sugar (FBS) and creatinine; normal results of the first neurological examination of the perineal area, lower limbs, lower limb reflexes, and bulbocavernosus reflex; having weight between 50 to 100 kg; not usage of other medicines; no signs of psychological disorders; confirmed diagnosis of chronic prostatitis; creatinine equal to or lower than 1.2 mg; platelet count over 100000/mm³; non-sensitivity to anti-epileptic drugs, pregabalin, thiazolidinediones, or other anti-diabetic agents. Exclusion criteria: Unwillingness to continue the study; major side-effects due to medical treatments. Sample size: 116 cases. Study intervention: Patients in control group will receive 2mg of terazosin tablets (Razak Company) plus 3mg of starch capsules (placebo). Patients in intervention group will receive 3mg of melatonin capsules daily for six weeks. Study outcomes: Evaluation and comparison of pain relief, urinary symptoms and side-effects of medications between two groups, based on the scoring system introduced by the National Institute of Health-Chronic Prostatitis Symptom Index (NIH-CPSI) and global response assessment (GRA) two, four and six weeks after intervention.

General information

Acronym

IRCT registration information

IRCT registration number: **IRCT2016071025507N4**
Registration date: **2016-07-19, 1395/04/29**
Registration timing: **prospective**

Last update:

Update count: **0**

Registration date

2016-07-19, 1395/04/29

Registrant information

Name

Ali Serous

Name of organization / entity

Arak University of Medical Sciences

Country

Iran (Islamic Republic of)

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Recruitment status

Recruitment complete

Funding source

Vice Chancellor for Research, Arak University of Medical Sciences

Expected recruitment start date

2016-08-22, 1395/06/01

Expected recruitment end date

2017-08-23, 1396/06/01

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

A clinical trial to comparison the effectiveness of melatonin and capsules containing starch (placebo) as an adjuvant therapy to control symptoms of chronic nonbacterial prostatitis patients

Public title

Control of chronic nonbacterial prostatitis symptoms

Purpose

Treatment

Inclusion/Exclusion criteria

Inclusion criteria: Age over 18 years; no prior history of other urinary system disorders such as urinary tract stones, neurogenic bladder, and urinary infections; no history of underlying diseases such as cirrhosis, renal failure, diabetes, or hypertension; normal levels of urine, fasting blood sugar (FBS), and creatinine; normal results on the first neurological examination of the perineal area, lower limbs, lower limb reflexes, and bulbocavernosus reflex; having weight between 50 to 100 kg; no use of other medicines; no signs of psychological disorders; confirmed diagnosis of chronic prostatitis; creatinine equal to or lower than 1.2 mg; platelet count over 100000/mm³; non-sensitivity to anti-epileptic drugs, pregabalin, thiazolidinediones, or other anti-diabetic agents. Exclusion criteria: Unwillingness to continue the study; 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: **116**

Randomization (investigator's opinion)

Randomized

Randomization description**Blinding (investigator's opinion)**

Double blinded

Blinding description**Placebo**

Used

Assignment

Parallel

Other design features

Randomization will be performed using block randomization.

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'Iam-Al-Hoda Street, Shahid Shiroodi Street

City

Arak

Postal code**Approval date**

2016-02-15, 1394/11/26

Ethics committee reference number

ARAKMU.REC.1394.309

Health conditions studied**1****Description of health condition studied**

Chronic nonbacterial prostatitis

ICD-10 code

N41.1

ICD-10 code description

Chronic prostatitis

Primary outcomes**1****Description**

Pain scale

Timepoint

Two, four and six weeks after intervention

Method of measurement

NIH-CPSI and GRA questionnaire

Secondary outcomes**1****Description**

Side-effects of pharmaceuticals including nausea, vomiting, hypotension, itching and drowsiness.

Timepoint

Two, four and six weeks after intervention

Method of measurement

Questionnaire

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

Control group: patients in this group will receive 2mg of terazosin tablets (Razak Company) plus 3mg of starch capsules (placebo).

Category

Treatment - Drugs

2

Description

Intervention group: patients in this group will receive 3mg of melatonin capsules daily for six weeks.

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, Pyrozi 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

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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

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Other areas of specialty/work

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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