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
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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'lam-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
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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

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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