

Clinical Trial Protocol

Iranian Registry of Clinical Trials

18 Jul 2026

Assessment the effect of Gabapentin as an assistive treatment in chronic nonbacterial prostatitis

Protocol summary

Study aim

Determining the effect of gabapentin as an assistive treatment in chronic nonbacterial prostatitis

Design

A pre- and a post-intervention clinical trial with an intervention group of 100 patients, without a control group, non-blinded.

Settings and conduct

Patients will be selected in a simple randomized manner, and the patient's age and information about the symptoms and about The factors that contribute to chronic non-bacterial prostatitis will be asked. an informed consent form is provided to the patient and our study will begin. Then, along with other prescription drugs, the patient will receive gabapentin capsules produced by Abidi Company at a dose of 100 mg orally twice daily. The treatment period will be 12 weeks. At the end of the course, patients will be given a response to treatment with a score of 1 to 10.

Participants/Inclusion and exclusion criteria

Inclusion criteria: -Age of 18 years old or more -Having pain in one or more this areas: groin,hypo-gastric, back pain, testis, penis, lower back, anal, and the area between the scrotum and anus for at least three months. -Having one or more of the following urinary symptoms: dysuria, frequency, delay at the beginning of urination, enuresis, the urgency. -Painful ejaculation -Erectile dysfunction exclusion criteria: -Chronic bacterial prostatitis -Acute prostatitis -Dissatisfied to participate in the study -Allergy to gabapentin

Intervention groups

Intervention group: adding Gabapentin to the usual treatment of patients with non-bacterial chronic prostatitis Control group: without a control group

Main outcome variables

Reducing pain in chronic non-bacterial prostatitis

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20180103038196N7**

Registration date: **2019-02-28, 1397/12/09**

Registration timing: **retrospective**

Last update: **2019-02-28, 1397/12/09**

Update count: **0**

Registration date

2019-02-28, 1397/12/09

Registrant information

Name

Amir Hossein Salimi Kordasiabi

Name of organization / entity

Country

Iran (Islamic Republic of)

Phone

+98 912 361 5549

Email address

hosseininejad.s.mohsen@goums.ac.ir

Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2018-02-20, 1396/12/01

Expected recruitment end date

2019-02-20, 1397/12/01

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Assessment the effect of Gabapentin as an assistive treatment in chronic nonbacterial prostatitis		Postal code 4326732561	
Public title Assessment the effect of Gabapentin in the treatment of chronic non-bacterial prostatitis		Approval date 2017-10-30, 1396/08/08	
Purpose Supportive		Ethics committee reference number IR.IAU.SHAHROOD.REC.1396.30	
Inclusion/Exclusion criteria Inclusion criteria: Age 18 or more Having pain in one or more areas of the groin,hypo-gastric, back pain, testicular, penis, lower back, anal, and the area between the scrotum and anus for at least three months Having one or more of the following urinary symptoms that include: dysuria, frequency, delay in beginning urination, enuresis, the urgency for urination Painful ejaculation Erectile dysfunction Exclusion criteria: Chronic bacterial prostatitis Acute prostatitis Dissatisfied to participate in the study Allergy to Gabapentin		Health conditions studied 1 Description of health condition studied Chronic nonbacterial prostatitis ICD-10 code N41.1 ICD-10 code description Chronic prostatitis	
Age From 18 years old		Primary outcomes 1 Description Reducing the pain caused by non-bacterial chronic prostatitis Timepoint Evaluation of pain after 12 weeks of treatment Method of measurement Visual Analogue Scale for pain	
Gender Male		Secondary outcomes empty	
Phase 3		Intervention groups 1 Description Intervention group: Patients with non-bacterial chronic prostatitis.the patient will receive Gabapentin capsules produced by abidi Company at a dose of 100 mg orally twice daily. The treatment period will be 12 weeks. At the end of the course, patients will be given a response to treatment with a score of 1 to 10. Category Treatment - Drugs	
Groups that have been masked <i>No information</i>		Recruitment centers 1 Recruitment center Name of recruitment center Khatam-ol-Anbia hospital (Shahrood) Full name of responsible person Niloufar Tajali Street address Khatam-al-Anbia hospital,facing Industrial university ,Daneshgah Blvd,Shahrood City	
Sample size Target sample size: 100			
Randomization (investigator's opinion) N/A			
Randomization description			
Blinding (investigator's opinion) Not blinded			
Blinding description			
Placebo Not used			
Assignment Single			
Other design features			
Secondary Ids empty			
Ethics committees 1 Ethics committee Name of ethics committee Ethics committee of Shahrood branch of Islamic Azad medical university Street address Shahrood University of Medical Sciences, Daneshgah Blv, Shahrood City Shahrood Province Semnan			

Shahrood
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Sponsors / Funding sources

1

Sponsor

Name of organization / entity
Islamic Azad University
Full name of responsible person
Research Deputy
Street address
Shahrood University of Medical Sciences, Daneshgah
Blv, Shahrood
City
Shahrood
Province
Semnan
Postal code
3614871151
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infoshahrood@yahoo.com

Grant name

Grant code / Reference number

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

Yes

Title of funding source

Islamic Azad University

Proportion provided by this source

100

Public or private sector

Private

Domestic or foreign origin

Domestic

Category of foreign source of funding

empty

Country of origin

Type of organization providing the funding

Persons

Person responsible for general inquiries

Contact

Name of organization / entity
Islamic Azad University
Full name of responsible person
Niloufar Tajali
Position
Medical student
Latest degree
A Level or less

Other areas of specialty/work

General Practitioner

Street address

Khatam-al-Anbia Hospital,Facing University of
Technology,Daneshgah Blvd,shahrood

City

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salimia92@yahoo.com

Person responsible for scientific inquiries

Contact

Name of organization / entity

Islamic Azad University

Full name of responsible person

Seyyed Vahid Sadr Bolurian

Position

Associate professor

Latest degree

Specialist

Other areas of specialty/work

Urology

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Person responsible for updating data

Contact

Name of organization / entity

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Full name of responsible person

Niloufar Tajali

Position

Medical student

Latest degree

A Level or less

Other areas of specialty/work

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Sharing plan**Deidentified Individual Participant Data Set (IPD)**

No - There is not a plan to make this available

Justification/reason for indecision/not sharing IPD

The dissatisfaction of a number of participants with the publication of data

Study Protocol

Undecided - It is not yet known if there will be a plan to make this available

Statistical Analysis Plan

Not applicable

Informed Consent Form

No - There is not a plan to make this available

Clinical Study Report

Not applicable

Analytic Code

Not applicable

Data Dictionary

Not applicable