Clinical Trial Protocol
Iranian Registry of Clinical Trials

08 Nov 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
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Amir Hossein Salimi Kordasiabi
Name of organization / entity
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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

Public title
Assessment the effect of Gabapentin in the treatment of chronic non-bacterial prostatitis
Purpose
Supportive
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
Age
From **18 years** old
Gender
Male

Phase
3
Groups that have been masked
No information
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
Postal code
4326732561
Approval date
2017-10-30, 1396/08/08
Ethics committee reference number
IR.IAU.SHAHROOD.REC.1396.30

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
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

Secondary outcomes

empty

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

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
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Sponsors / Funding sources

1

Sponsor
Name of organization / entity
Islamic Azad University
Full name of responsible person
Research Deputy
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Shahrood University of Medical Sciences, Daneshgah Blv, Shahrood
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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
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Person responsible for updating data

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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