Clinical Trial Protocol
Iranian Registry of Clinical Trials

19 Jun 2026

Evaluation of the effect of Erectofix device in solving prostatitis symptoms and complications

Protocol summary

Study aim
Treatment of patients with chronic prostatitis by effective methods

Design
The study is conducted as a clinical trial with a control group in parallel on 60 patients

Settings and conduct
60 eligible patients are randomly assigned to the intervention group or the control group, and this process continues until the sample size is completed. Standard medical treatment will be given to all patients, as well as the consent form will be explained to all patients about the process of intervention and the complications caused by it. All patients will have the permission to withdraw from the intervention at any time after hearing the explanation of the project manager. When diagnosed and before starting the treatment, a questionnaire related to chronic prostatitis (NIH-CPSI score) will be filled and after the end of the course Re-treatment of this questionnaire completion and necessary comparisons in resolving the symptoms of the patient's face

Participants/Inclusion and exclusion criteria
Inclusion criteria include age between 20-65 years. Has symptoms of chronic prostatitis Exclusion criteria: history of urological surgery leading to regional nerve amputation, regional vascular injury A history of trauma to the genital area that caused neurological or vascular defects in the area History of medical diseases (diabetes, high blood pressure, blood lipid disorders, thyroid disorders and severe depression

Intervention groups
The intervention in the form of Higgs energy transfer with the help of vibratory stimulation (PV) embedded in the Orthofix device, is introduced by two arms, simultaneously, to both the lower and upper levels of the penis, which is carried out. patients are treated twice a week for a period of 5 consecutive sessions. Standard medical treatment will be given to all patients.Standard medical treatment will be given to control group.

Main outcome variables
prostatitis

General information

Reason for update

Acronym

IRCT registration information
IRCT registration number: **IRCT20230408057854N2**
Registration date: **2023-05-13, 1402/02/23**
Registration timing: **prospective**

Last update: **2023-05-13, 1402/02/23**
Update count: **0**

Registration date
2023-05-13, 1402/02/23

Registrant information

Name
hossein rahnama

Name of organization / entity

Country
Iran (Islamic Republic of)

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+98 56 3282 2705

Email address
drhossein2020@sbmu.ac.ir

Recruitment status
Recruitment complete

Funding source

Expected recruitment start date
2023-06-22, 1402/04/01

Expected recruitment end date
2024-06-21, 1403/04/01

Actual recruitment start date
empty

Actual recruitment end date
empty

Trial completion date
empty

Scientific title
Evaluation of the effect of Erectofix device in solving prostatitis symptoms and complications

Public title
Evaluation of the effect of Erectofix device in solving prostate Inflammation symptoms and complications

Purpose
Treatment

Inclusion/Exclusion criteria
Inclusion criteria:
Age between 20-65 years Have symptoms of chronic prostatitis
Exclusion criteria:
History of urological surgery leading to regional nerve cutting, regional vascular damage A history of trauma to the genital area that caused neurological or vascular defects in the area History of medical diseases (diabetes, high blood pressure, blood lipid disorders, thyroid disorders and severe depression)

Age
From **20 years** old to **65 years** old

Gender
Male

Phase
N/A

Groups that have been masked

- Outcome assessor
- Data analyser

Sample size
Target sample size: **60**

Randomization (investigator's opinion)
Randomized

Randomization description
First, by using the Random number generation plugin in Excel software, a table of random numbers from 1 to 60 is prepared in a non-sequential and scattered manner, and intervention and control are done by assigning numbers to two groups of 60 people. The randomization process is done by the study methodology consultant, and the clinical researchers do not know about the randomization process, and only randomized codes from 1 to 60 will be provided to them.

Blinding (investigator's opinion)
Single blinded

Blinding description
After selecting the samples, none of the sampled people will know about randomization and the process of allocation to groups. Doctors are given a table of coded numbers in advance and patients are included in the study in the order of the numbers in the table. Therefore, the present study is double-blind. All patients receive routine medical treatment and all patients are placed under the Orthofix device, but the desired wavelength is given to the case group, but not to the control group.

Placebo
Not used

Assignment
Parallel

Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee
Name of ethics committee
Shahid Beheshti University of Medical Sciences Ethics Committee
Street address
Shohadaye Tajrish Hospital,Shahradari St.Postal code1989934148
City
Tehran
Province
Tehran
Postal code
1989934148

Approval date
2022-11-13, 1401/08/22

Ethics committee reference number
IR.SBMU.RETECH.REC.1401.540

Health conditions studied

1

Description of health condition studied
prostatitiis

ICD-10 code
N41

ICD-10 code description
Inflammatory diseases of prostate

Primary outcomes

1

Description
Pain and discomfort in the perineum

Timepoint
A course of 5 consecutive sessions twice a week

Method of measurement
Questionnaire related to chronic prostatitis (NIH-CPSI score)

Secondary outcomes

empty

Intervention groups

1

Description
Using the Higgs laser

Category
Treatment - Devices

2

Description
Control group: standard treatment
Category
Treatment - Drugs

Recruitment centers

1

Recruitment center
Name of recruitment center
Shohada Tajrish Hospital
Full name of responsible person
Hossein Rahnama
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Shohada Tajrish Hospital, Shahradari St.Postal code1989934148
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rahnama2010@gmail.com

Sponsors / Funding sources

1

Sponsor
Name of organization / entity
Shahid Beheshti University of Medical Sciences
Full name of responsible person
Afshin Zarghi
Street address
Yaman st, Daneshjoo Blvd, Velenjak st
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1985717443
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info@sbmu.ac.ir
Grant name
Grant code / Reference number
Is the source of funding the same sponsor organization/entity?
Yes
Title of funding source
Shahid Beheshti University of Medical Sciences
Proportion provided by this source
50
Public or private sector
Public
Domestic or foreign origin
Domestic
Category of foreign source of funding
empty
Country of origin
Type of organization providing the funding
Academic

Person responsible for general inquiries

Contact
Name of organization / entity
Shahid Beheshti University of Medical Sciences
Full name of responsible person
Hossein Rahnama
Position
Resident
Latest degree
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Other areas of specialty/work
Urology
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Person responsible for updating data

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Position

Resident

Latest degree

Medical doctor

Other areas of specialty/work

Urology

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Sharing plan

Deidentified Individual Participant Data Set (IPD)

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

Study Protocol

Yes - There is a plan to make this available

Statistical Analysis Plan

Yes - There is a plan to make this available

Informed Consent Form

Yes - There is a plan to make this available

Clinical Study Report

Yes - There is a plan to make this available

Analytic Code

Not applicable

Data Dictionary

Not applicable

Title and more details about the data/document

All data is potentially shareable after de-identifying individuals

When the data will become available and for how long

The access period starts immediately after the results are printed

To whom data/document is available

All researchers

Under which criteria data/document could be used

Any use of documents should be done in coordination with the researcher

From where data/document is obtainable

Hossein Rahnama via the email address below rahnama2010@gmail.com

What processes are involved for a request to access data/document

Send an email to the researcher

Comments