

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)

Phone

+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 code 1989934148

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
Street address
Shohada Tajrish Hospital, Shahradari St.Postal
code1989934148
City
Tehran
Province
Tehran
Postal code
1989934148
Phone
+98 21 2271 8000
Email
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
City
Tehran
Province
Tehran
Postal code
1985717443
Phone
+98 21 23871
Email
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
Medical doctor
Other areas of specialty/work
Urology
Street address
Shohada Tajrish Hospital,Shahradari St.Postal
code1989934148
City
Tehran
Province
Tehran
Postal code
1989934148
Phone
+98 21 2271 8002
Email
rahnama2010@gmail.com

Person responsible for scientific inquiries

Contact

Name of organization / entity
Shahid Beheshti University of Medical Sciences
Full name of responsible person
Hossein Rahnama
Position
Resident
Latest degree
Medical doctor
Other areas of specialty/work
Urology
Street address
Shohada Tajrish Hospital,Shahradari St.Postal
code1989934148
City
Tehran
Province
Tehran
Postal code
1989934148
Phone

+98 21 2271 8000

Email

rahnama2010@gmail.com

Person responsible for updating data

Contact

Name of organization / entity

Shahid Beheshti University of Medical Sciences

Full name of responsible person

Hossein Rahnama

Position

Resident

Latest degree

Medical doctor

Other areas of specialty/work

Urology

Street address

Shohada Tajrish Hospital,Shahradari St.Postal
code1989934148

City

Tehran

Province

Tehran

Postal code

1989934148

Phone

+98 21 2271 8002

Email

rahnama2010@gmail.com

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