

Clinical Trial Protocol

Iranian Registry of Clinical Trials

19 Jun 2026

Efficacy of Erectofix device in the patients with erectile dysfunction

Protocol summary

Study aim

Evaluation of the effectiveness of Erectofix device in solving the problem of erectile dysfunction

Design

A randomized clinical trial (phase III) single-blind with control group, 28 patient in each group. Randomization will be done with excel software

Settings and conduct

Patients who enter the study, complete the International Erectile function Questionnaire and randomly assigned to each group. In the intervention group, Higgs energy transfer is performed with the help of PVS (penile vibratory stimulation) embedded in the Erectofix device. This energy transfer is transmitted by both arms simultaneously to both the lower and upper levels of the penis and causes vibrational/vibratory stimulation to both the back and top of the penis, as well as to each branch of the pudendal nerve. All these steps are performed by a trained urologist and technician. Both groups are not excluded from routine treatment. After the study, the questionnaire is completed again.

Participants/Inclusion and exclusion criteria

Inclusion criteria: All men aged 30 to 55 with erectile dysfunction referring to the Urology Clinic of Shahada Tajrish Hospital exclusion criteria: History of urological surgery leading to area nerve rupture, area vascular damage, History of orchiectomy, History of penis trauma with venous arterial fistula, History of genital trauma with neurological or vascular deflection., History of antipsychotic drugs and benzodiazepines, anti-androgens assumption, History of diseases (diabetes, hypertension, hyperlipidemia, thyroid disorders and severe depression), History of smoking, alcohol and drugs, history of occupational exposure to chemicals and radioactive substances.

Intervention groups

1- Treatment group with Erectofix device 2- Control group without any intervention (routine treatment)

Main outcome variables

Erectile dysfunction

General information

Reason for update

Acronym

مشکل اختلال در نعوظ

IRCT registration information

IRCT registration number: **IRCT20111121008146N40**

Registration date: **2022-08-21, 1401/05/30**

Registration timing: **prospective**

Last update: **2022-08-21, 1401/05/30**

Update count: **0**

Registration date

2022-08-21, 1401/05/30

Registrant information

Name

Mohammadreza Razaghi

Name of organization / entity

Laser application in medical sciences research center

Country

Iran (Islamic Republic of)

Phone

+98 21 2271 8021

Email address

laser.cntr@sbmu.ac.ir

Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2022-08-22, 1401/05/31

Expected recruitment end date

2023-08-22, 1402/05/31

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Efficacy of Erectofix device in the patients with erectile dysfunction

Public title

Evaluation of the effectiveness of Erectofix device for erectile dysfunction

Purpose

Treatment

Inclusion/Exclusion criteria

Inclusion criteria:

Age between 20-55 years Has an erectile dysfunction problem

Exclusion criteria:

History of urological surgery with area nerve rupture, area vascular damage History of orchiectomy History of penile trauma with venous arterial fistula History of trauma to the genital area that has caused neurological or vascular defects in the area. History of taking antipsychotic drugs and benzodiazepines, anti-androgens History of medical conditions (diabetes, hypertension, hyperlipidemia, thyroid disorders and major depression) History of smoking, alcohol and drugs, as well as a history of occupational exposure to chemicals and radioactive substances.

Age

From **30 years** old to **55 years** old

Gender

Male

Phase

3

Groups that have been masked

- Data analyser

Sample size

Target sample size: **56**

Randomization (investigator's opinion)

Randomized

Randomization description

Using Excel software, we generate random numbers. Even numbers are assigned to the intervention group and odd numbers to the control group. The production of random numbers continues until the samples of each group are completed.

Blinding (investigator's opinion)

Single blinded

Blinding description

The statistical analyst will analyze the grouping of the data in the form of A and B and will not know which is the intervention group and which is the control group.

Placebo

Not used

Assignment

Parallel

Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee

Organizational Committee of Ethics in Biomedical Research

Street address

Tehran - Shahid Chamran Highway Yemen Street - Shahid Arabi Street next to Ayatollah Taleghani Hospital

City

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Province

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Postal code

1985717443

Approval date

2022-05-29, 1401/03/08

Ethics committee reference number

IR.SBMU.RETECH.REC.1401.106

Health conditions studied

1

Description of health condition studied

Erectile dysfunction

ICD-10 code

N52.9

ICD-10 code description

Male erectile dysfunction, unspecified

Primary outcomes

1

Description

Erectile dysfunction

Timepoint

Before intervention and one week after the last intervention

Method of measurement

Male sexual function refers to the score that a person obtains in the International Male Erectile Performance Index Questionnaire (Rosen et al., 1997).

Secondary outcomes

empty

Intervention groups

1

Description

Intervention group: Higgs energy transfer is performed with penile vibratory stimulation embedded in the Erectofix device. This energy is transmitted by both arms simultaneously to the lower and upper levels of the penis and vibrational/vibratory stimulation to the back and top

of the penis, as well as to each branch of the pudendal nerve. A trained urologist and technician perform all these steps. The waves of this device are RF and radio frequency waves. Of course, these waves do no harm to the body and have the highest compatibility with the body.

Category

Treatment - Devices

2**Description**

Control group: Routine treatment is performed.

Category

Treatment - Drugs

Recruitment centers**1****Recruitment center****Name of recruitment center**

Urology Clinic of Shohada Tajrish Hospital

Full name of responsible person

Mohammad Reza Razzaghi

Street address

Shohada Tajrish Hospital-Shahrdari st-Tajrish square

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Sponsors / Funding sources**1****Sponsor****Name of organization / entity**

Shahid Beheshti University of Medical Sciences

Full name of responsible person

Afshin Zarghi, Vice-Chancellor of Research Affairs

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Shahid Beheshti University of medical sciences,
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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

100

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**

Laser Application Research Center in Medical Sciences

Full name of responsible person

Mohammad Reza Razzaghi

Position

Professor of Urology, Shahid Beheshti University of Medical Sciences

Latest degree

Specialist

Other areas of specialty/work

Urology

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Person responsible for scientific inquiries**Contact****Name of organization / entity**

Shahid Beheshti University of Medical Sciences

Full name of responsible person

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Position

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Latest degree

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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

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

Statistical Analysis Plan

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

Informed Consent Form

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

Clinical Study Report

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

Analytic Code

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

Data Dictionary

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