Clinical Trial Protocol
Iranian Registry of Clinical Trials

04 Nov 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 defection., 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
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Iran (Islamic Republic of)
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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
Tehran

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Tehran

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

Street address
Shahid Beheshti University of medical sciences, Yaman st, Daneshjoo Blvd

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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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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