Clinical Trial Protocol
Iranian Registry of Clinical Trials

17 Sep 2026

The effect of low-intensity shock waves (LI-ESWT) in improving erectile function in patients with erectile dysfunction not responding to PDE-5 inhibitors

Protocol summary

Study aim
The effect of low-intensity shock waves (LI-ESWT) in improving erectile function in patients with erectile dysfunction not responding to PDE-5 inhibitors

Design
The study will be performed as an open clinical trial without blindness

Settings and conduct
The study will be performed in a private urology clinic in Rasht. The study will be performed as an open clinical trial without blindness...

Participants/Inclusion and exclusion criteria
Inclusion criteria: age more than 40 years; lack of therapeutic response to phosphodiesterase inhibitors 5. Exclusion criteria: history of psychological disorders based on the Beck standard questionnaire; history of previous radical prostatectomy; history of pelvic radiotherapy; history of malignancy in the last five years; use of anti-androgens, anticoagulants, thiazides, non-specific antiblockers, opioids and drugs; coronary artery disease; heart failure.

Intervention groups
Intervention group: Low-intensity shock waves (LI-ESWT) with energy density of 0.160 mJ/mm2 and 6HZ-8HZ frequencies and the total number of 6000 shock, once a week for six consecutive weeks

Main outcome variables
International Index of Erectile Function

General information

Reason for update
Due to the fact that in the past, the preliminary steps to register a clinical trial in the system started earlier than receiving the ethics approvals, and by taking the approval code, the steps were completed and the proposal was sent, and sometimes it took several months to register in IRCT, so the expected date for starting the study was sometimes much earlier than the due date for it.This project also started about 14 months after the expected date due to financial problems and many improvements in the implementation method. Currently, to prepare the article, it is necessary to modify the dates of start and finish in the system.

Acronym

IRCT registration information
IRCT registration number: **IRCT201710024582N6**
Registration date: **2017-11-05, 1396/08/14**
Registration timing: **prospective**

Last update: **2022-06-07, 1401/03/17**
Update count: **1**

Registration date
2017-11-05, 1396/08/14

Registrant information

Name
Ali Hamidi Madani

Name of organization / entity
Urology Research Center, Guilan University of Medical Sciences

Country
Iran (Islamic Republic of)

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+98 13 1552 5259

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Recruitment status
Recruitment complete

Funding source
Urology Research Center, Guilan University of Medical Sciences

Expected recruitment start date
2016-06-21, 1395/04/01

Expected recruitment end date
2017-09-23, 1396/07/01
Actual recruitment start date
2017-11-07, 1396/08/16
Actual recruitment end date
2018-07-23, 1397/05/01
Trial completion date
2018-08-23, 1397/06/01

Scientific title
The effect of low-intensity shock waves (LI-ESWT) in improving erectile function in patients with erectile dysfunction not responding to PDE-5 inhibitors

Public title
The effect of low-intensity shock waves (LI-ESWT) in patients with erectile dysfunction
Purpose
Treatment
Inclusion/Exclusion criteria
Inclusion criteria:
age more than 40 years; passing more than 6 months from the onset of the disease; having a stable sex in the last three months; lack of therapeutic response to phosphodiesterase inhibitors 5; lack of experience in the use of drugs or non-medical therapies for the treatment of erectile dysfunction in the last three months
Exclusion criteria:
history of psychological disorders based on the Beck standard questionnaire; history of neurological diseases; history of previous radical prostatectomy; history of pelvic radiotherapy; history of malignancy in the last five years; use of anti-androgens, anticoagulants, thiazides, non-specific antiblockers, antipsychotics, antidepressants , anxiolytics, opioids and drugs; alcohol abuse; severe lower urinary tract symptoms (LUTS); history of urethritis; coronary artery disease; heart failure; thyroid disorders; penile or urethra anomalies
Age
From **40 years** old to **139 years** old
Gender
Male

Phase
N/A
Groups that have been masked
No information
Sample size
Target sample size: **128**
Actual sample size reached: **128**
Randomization (investigator's opinion)
N/A
Randomization description
Blinding (investigator's opinion)
Not blinded
Blinding description
Placebo
Not used
Assignment
Single
Other design features
The study will be performed as an open clinical trial without blindness.

Secondary Ids

empty

Ethics committees

1

Ethics committee
Name of ethics committee
Ethics committee of Guilan University of Medical Sciences
Street address
Namjoo Street
City
Rasht
Province
Guilan
Postal code
41938-93345
Approval date
2016-06-21, 1395/04/01
Ethics committee reference number
IR.GUMS.REC.1395.106

Health conditions studied

1

Description of health condition studied
Erectile dysfunction
ICD-10 code
F52.2
ICD-10 code description
Failure of genital response

Primary outcomes

1

Description
International Index of Erectile Function
Timepoint
Before intervention, at the end of intervention, 3 and 6 months after intervention
Method of measurement
The International Index of Erectile Function (IIEF) questionnaire

Secondary outcomes

empty

Intervention groups

1

Description
Low-intensity shock waves (LI-ESWT) with energy density of 0.160 mJ/mm2 and 6HZ-8HZ frequencies and the total number of 6000 shock, once a week for six consecutive weeks

Category
Rehabilitation

Recruitment centers

1

Recruitment center
Name of recruitment center
Razi Hospital
Full name of responsible person
Dr. Mahmoud Shabanipour
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Sponsors / Funding sources

1

Sponsor
Name of organization / entity
Urology Research Centre, Guilan University of Medical Sciences
Full name of responsible person
Head of Urology Research Centre, Dr. Siavsh Falahatkar
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Urology Research Centre, Razi Hospital, Sardar Jangal Street, Rasht
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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
Urology Research Centre, Guilan 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
Urology Research Center, Guilan University of Medical Sciences
Full name of responsible person
Dr. Mahmoud Shabanipour
Position
Resident of Urology/ Co worker
Latest degree
Specialist
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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