

Clinical Trial Protocol

Iranian Registry of Clinical Trials

09 Jul 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 antblockers, 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)

Phone

+98 13 1552 5259

Email address

hamidimadani@gums.ac.ir

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 antblockers, 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

Street address

Razi Hospital, Sardar Jangal Street, Rasht

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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

Other areas of specialty/work

Urology

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

Urology Research Center, Guilan University of Medical Sciences

Full name of responsible person

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Latest degree

Specialist

Other areas of specialty/work

Urology

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Person responsible for updating data

Contact

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Rasht
Province

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