

# Clinical Trial Protocol

## Iranian Registry of Clinical Trials

10 Jun 2026

### Study of the effect of low-intensity shock waves (LI-ESWT) in patients with erectile dysfunction in comparison with medical treatment

#### Protocol summary

##### Study aim

Evaluation of the effect of low intensity shock waves in the treatment of patients with erectile dysfunction and comparison with standard medical treatment (5 phosphodiesterase inhibitors)

##### Design

A randomized controlled clinical trial with parallel, non-blinded, randomized trials with computer-generated random lists

##### Settings and conduct

Men with vasculogenic erectile dysfunction who refer to the Urology Department of Imam Reza Hospital are randomly divided into case and control groups (using computer-generated random lists). The case group will be treated with ESWT weekly for 6 weeks. The control group will receive standard drug therapy (tadalafil) during this time. Patients in both groups will be assessed by the IIEF questionnaire at baseline, week 10 (4 weeks after treatment) and then every three months to one year.

##### Participants/Inclusion and exclusion criteria

Inclusion criteria : men over 30 years old with at least 6 months vasculogenic erectile dysfunction. Exclusion criteria :Other erectile disorders include neurogenic, psychogenic and idiopathic disorders History of pelvic surgery or radiotherapy Use of anti-coagulants, use of anti-androgen Anatomic penis deformities or prosthesis Total testosterone lower than 8 nmol /dl, Advanced heart or lung disease, neurological or psychiatric illness Pregnant wife International Index of Erectile Dysfunction More Than 25

##### Intervention groups

The intervention group included men over 30 years old who have vasculogenic erectile dysfunction at least 6 month and receive the intervention of " low intensity extra corporal shock wave" . The control group included men over 30 years old who have vasculogenic erectile dysfunction at least 6 mounth and receive the intervention of 5- phosphodiesterase inhibitor drugs.

#### Main outcome variables

Increased at least 5 points on IIEF Erectile Dysfunction Questionnaire

#### General information

##### Reason for update

##### Acronym

LI-ESWT

##### IRCT registration information

IRCT registration number: **IRCT20190824044601N1**

Registration date: **2019-09-25, 1398/07/03**

Registration timing: **registered\_while\_recruiting**

Last update: **2019-09-25, 1398/07/03**

Update count: **0**

##### Registration date

2019-09-25, 1398/07/03

##### Registrant information

##### Name

Seyed Hamed Ghadamgahi moghaddam

##### Name of organization / entity

##### Country

Iran (Islamic Republic of)

##### Phone

+98 51 3513 3648

##### Email address

ghadamgahimh951@mums.ac.ir

##### Recruitment status

**Recruitment complete**

##### Funding source

##### Expected recruitment start date

2019-09-01, 1398/06/10

##### Expected recruitment end date

2020-07-22, 1399/05/01

##### Actual recruitment start date

empty

**Actual recruitment end date**

empty

**Trial completion date**

empty

**Scientific title**

Study of the effect of low-intensity shock waves (LI-ESWT) in patients with erectile dysfunction in comparison with medical treatment

**Public title**

The effect of low-intensity shock waves (LI-ESWT) in patients with erectile dysfunction in comparison with medical treatment

**Purpose**

Treatment

**Inclusion/Exclusion criteria****Inclusion criteria:**

Men over 30 years old with at least 6 months elapsed since their erectile dysfunction and vasculogenic erectile dysfunction

**Exclusion criteria:**

Other erectile disorders include neurogenic, psychogenic and idiopathic disorders History of pelvic surgery or radiotherapy Use of anti-coagulants, use of anti-androgen Anatomic penis deformities or prosthesis Total testosterone lower than 8 nmol /dl, Advanced heart or lung disease, neurological or psychiatric illness Pregnant wife International Index of Erectile Dysfunction More Than 25

**Age**

From 30 years old

**Gender**

Male

**Phase**

N/A

**Groups that have been masked**

No information

**Sample size**

Target sample size: 60

**Randomization (investigator's opinion)**

Randomized

**Randomization description**

Simple randomization individually using random number table provided by computer

**Blinding (investigator's opinion)**

Not blinded

**Blinding description****Placebo**

Not used

**Assignment**

Parallel

**Other design features****Secondary Ids**

empty

**Ethics committees****1****Ethics committee****Name of ethics committee**

Ethics committee of Mashhad University of Medical Sciences

**Street address**

No.13 ,Shahed 18 Aven.,Shahed Blvd.,Mashhad Town

**City**

Mashhad

**Province**

Razavi Khorasan

**Postal code**

9189774347

**Approval date**

2019-06-03, 1398/03/13

**Ethics committee reference number**

IR.MUMS.MEDICAL.REC.1398.166

**Health conditions studied****1****Description of health condition studied**

Male erectile dysfunction

**ICD-10 code**

F52.2

**ICD-10 code description**

Sexual arousal disorders

**Primary outcomes****1****Description**

Increased at least 5 points on IIEF Erectile Dysfunction Questionnaire

**Timepoint**

The case group will be treated with ESWT weekly for 6 weeks. The control group will receive standard drug therapy (tadalafil) during this period. Patients in both groups will be evaluated at baseline, week 10 (4 weeks after treatment) and then every three months to one year

**Method of measurement**

International Index of Erectile Function Questionnaire

**Secondary outcomes****1****Description**

Score on Erection Hardness Score (EHS) questionnaire to over 3 in men with a lower or equal initial score

**Timepoint**

At baseline, 10 weeks (4 weeks after treatment) and then every three months to one year

**Method of measurement**

Erection Hardness Score questionnaire

## Intervention groups

1

### Description

Men over 30 years old with at least 6 months elapsed since their erectile dysfunction and vasculogenic erectile dysfunction

### Category

Treatment - Other

## Recruitment centers

1

### Recruitment center

#### Name of recruitment center

Urology Clinic of Imam Reza Hospital

#### Full name of responsible person

Kamyar Tavakoli Tabasi

#### Street address

No.13 ,Shahed 18 Aven.,Shahed Blvd.,Mashhad Town

#### City

Mashhad

#### Province

Razavi Khorasan

#### Postal code

9189774347

#### Phone

+98 51 3854 3031

#### Email

tavakolik@mums.ac.ir

## Sponsors / Funding sources

1

### Sponsor

#### Name of organization / entity

Mashhad University of Medical Sciences

#### Full name of responsible person

محسن تفقدي

#### Street address

University Street, Qureshi Building

#### City

Mashhad

#### Province

Razavi Khorasan

#### Postal code

91388-13944

#### Phone

+98 51 3841 2081

#### Email

TafaghodiM@mums.ac.ir

#### Grant name

#### Grant code / Reference number

#### Is the source of funding the same sponsor organization/entity?

Yes

#### Title of funding source

Mashhad 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

Mashhad University of Medical Sciences

#### Full name of responsible person

Seyed Hamed Ghadagami Moghaddam

#### Position

Resident

#### Latest degree

Medical doctor

#### Other areas of specialty/work

Urology

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GhadamgahiMH951@mums.ac.ir

## Person responsible for scientific inquiries

### Contact

#### Name of organization / entity

Mashhad University of Medical Sciences

#### Full name of responsible person

Kamyar Tavakoli Tabasi

#### Position

Associate Professor

#### Latest degree

Specialist

#### Other areas of specialty/work

Urology

#### Street address

Mashhad - Imam Reza Hospital

#### City

Mashhad

#### Province

Razavi Khorasan

#### Postal code

9137913316

#### Phone

+98 51 3854 3031

#### Email

## Person responsible for updating data

### Contact

**Name of organization / entity**

Mashhad University of Medical Sciences

**Full name of responsible person**

Seyed Hamed Ghadagami Moghaddam

**Position**

Resident

**Latest degree**

Medical doctor

**Other areas of specialty/work**

Urology

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## Sharing plan

**Deidentified Individual Participant Data Set (IPD)**

Yes - There is 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**

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

**Analytic Code**

Yes - There is a plan to make this available

**Data Dictionary**

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

**Title and more details about the data/document**

these files will be presented upon request: Patients` data after removing their identity, Research protocol, statistical methods used in this study and written informed consent.

**When the data will become available and for how long**

data will be available 3 months after the article has been published

**To whom data/document is available**

Any researcher who needs our data to accomplish his research

**Under which criteria data/document could be used**

The researcher should use these data only in their related research and should mention the reference

**From where data/document is obtainable**

Researchers should send their request to Dr.Kamyar Tavakoli Tabassi via email. Email:tavakolik@mums.ac.ir

**What processes are involved for a request to access data/document**

Researchers should send their request for data that includes their reasons for using the data and their study protocols and aims. The request will be answered during 14 business days

**Comments**