Clinical Trial Protocol
Iranian Registry of Clinical Trials

17 Sep 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)

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+98 51 3513 3648

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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
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No.13 ,Shahed 18 Aven.,Shahed Blvd.,Mashhad Town
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tavakolik@mums.ac.ir

Sponsors / Funding sources

1

Sponsor
Name of organization / entity
Mashhad University of Medical Sciences
Full name of responsible person
محسن تفقدی
Street address
University Street, Qureshi Building
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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
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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Person responsible for scientific inquiries

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Associate Professor
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Person responsible for updating data

Contact

Name of organization / entity
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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