Clinical Trial Protocol
Iranian Registry of Clinical Trials

07 Nov 2026

evaluation of the effectiveness of shock wave therapy in drag-resistant impotence

Protocol summary

Study aim
Evaluation of effectiveness of shock wave therapy in patients with erectile dysfunction
Design
Clinical trial without control group, without parallel group, without randomization on 50 patients.the outcome assessment was binded.
Settings and conduct
Patients will be recruited from the urology outpatient clilc of Emam Reza hospital.After providing a detailed explanation of the study aims and obtaining informed consent, eligible participants will be enrolled. The intervention will consist of one session per week of shockwave therapy for 6 weeks, with an energy flux density of 0.25 millijoules per square millimeter. Participants will then be followed up at 3 months post-treatment. The international index of erectile function (IIEF) questionnaire will be used to assess treatment response and evaluate changes in erectile function.
Participants/Inclusion and exclusion criteria
Inclusion criteria:All patients who dont be treated with maximum dose of PDEi drugs for 4 times Exclusion criteria: Lack of consent to participate in the study and the presence of contraindications for performing shockwave therapy such as hemodynamic disturbances
Intervention groups
All patients with erectile dysfunction who dont be treated with PDEi drugs
Main outcome variables
1- improve orgasmic performance 2- improve libido 3- improve erectile function 4- improve sexual satisfaction 5- overall satisfaction of the individual

General information

Reason for update
Acronym
IRCT registration information
IRCT registration number: **IRCT20230125057230N1**
Registration date: **2023-08-09, 1402/05/18**
Registration timing: **registered_while_recruiting**

Last update: **2023-08-09, 1402/05/18**
Update count: **0**
Registration date
2023-08-09, 1402/05/18

Registrant information
Name
aida jamlou
Name of organization / entity
Country
Iran (Islamic Republic of)
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Recruitment status
Recruitment complete
Funding source

Expected recruitment start date
2023-03-13, 1401/12/22
Expected recruitment end date
2023-09-22, 1402/06/31
Actual recruitment start date
empty
Actual recruitment end date
empty
Trial completion date
empty

Scientific title
evaluation of the effectiveness of shock wave therapy in drag-resistant impotence

Public title
evaluation of the treatment method of nephrolithiasis with with shock wave in infertility

Purpose
Treatment
Inclusion/Exclusion criteria
Inclusion criteria:
all patient with erectile dysfunction who dont be treated with PDEi drugs
Exclusion criteria:
Age
From **18 years** old to **80 years** old
Gender
Both

Phase
N/A
Groups that have been masked
No information
Sample size
Target sample size: **31**
Randomization (investigator's opinion)
N/A
Randomization description
Blinding (investigator's opinion)
Not blinded
Blinding description
Placebo
Not used
Assignment
Single
Other design features
during this study, for 6 weeks and every week a session of shockwave therapy with 0.25mJ/mm2 energy was performed for patients and follow up three months later

Secondary Ids

empty

Ethics committees

1

Ethics committee
Name of ethics committee
کمیته اخلاق دانشگاه علوم پزشکی تبریز
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no.13.dr hesabi square.shahgoli.tabriz.iran
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Approval date
2023-05-08, 1402/02/18
Ethics committee reference number
IR.TBZMED.REC.1402.102

Health conditions studied

1

Description of health condition studied
erectile dysfunction
ICD-10 code
ICD-10 code description

Primary outcomes

1

Description
erection
Timepoint
at the beginning of study and 3 months after shockwave therapy
Method of measurement
IIEF questionnaire

Secondary outcomes

empty

Intervention groups

1

Description
Intervention group: patients with erectile dysfunction that can't have appropriate erection after receiving maximum dose of PDE5i drugs for 4 times
Category
Treatment - Devices

Recruitment centers

1

Recruitment center
Name of recruitment center
urology clinic of Emma reza hospital
Full name of responsible person
faraji
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Sponsors / Funding sources

1

Sponsor
Name of organization / entity
Tabriz University of Medical Sciences
Full name of responsible person

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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
Tabriz 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
Tabriz University of Medical Sciences

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Position
medical student

Latest degree
A Level or less

Other areas of specialty/work
General Practitioner

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Latest degree
Subspecialist

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Urology

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Sharing plan

Deidentified Individual Participant Data Set (IPD)
No - There is not a plan to make this available

Justification/reason for indecision/not sharing IPD
there is no information

Study Protocol
No - There is not a plan to make this available

Statistical Analysis Plan
No - There is not a plan to make this available

Informed Consent Form
No - There is not a plan to make this available

Clinical Study Report

No - There is not a plan to make this available

Analytic Code

No - There is not a plan to make this available

Data Dictionary

No - There is not a plan to make this available