

# Clinical Trial Protocol

## Iranian Registry of Clinical Trials

09 Jul 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 blinded.

##### Settings and conduct

Patients will be recruited from the urology outpatient clinic 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)

###### Phone

+98 41 3477 2809

###### Email address

aidajamlou@yahoo.com

##### 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

##### Street address

no.13.dr hesabi square.shahgoli.tabriz.iran

##### City

tabriz

##### Province

East Azarbaijan

##### Postal code

۵۱۶۶۸۱۱۷۰۷

#### 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

##### Street address

no13.dr hesabi square.shahgoli.tabriz.iran

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##### Postal code

5166811707

##### Phone

+98 914 427 2432

##### Email

aidajamlou@yahoo.com

## Sponsors / Funding sources

### 1

#### Sponsor

##### Name of organization / entity

Tabriz University of Medical Sciences

##### Full name of responsible person

dr tayebi

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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

**Full name of responsible person**

aida jamlou

**Position**

medical student

**Latest degree**

A Level or less

**Other areas of specialty/work**

General Practitioner

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## Person responsible for scientific inquiries

**Contact**

**Name of organization / entity**

Tabriz University of Medical Sciences

**Full name of responsible person**

dr mohsen Mohammad Rahimi

**Position**

assistant professor

**Latest degree**

Subspecialist

**Other areas of specialty/work**

Urology

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## Person responsible for updating data

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Tabriz University of Medical Sciences

**Full name of responsible person**

dr mohsen Mohammad Rahimi

**Position**

assistant professor

**Latest degree**

Subspecialist

**Other areas of specialty/work**

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