

# Clinical Trial Protocol

## Iranian Registry of Clinical Trials

27 Jun 2026

### Comparative study of extracorporeal shock wave therapy (ESWT) and Intra-Plaque Injection of Verapamil in the Treatment of Peyronie's Disease

#### Protocol summary

##### Study aim

Comparative study of extracorporeal shock wave therapy and Intra-Plaque Injection of Verapamil in the Treatment of Peyronie's Disease

##### Design

This study is a non-blinded clinical trial with a parallel design and a control group. The study population will include all patients diagnosed with peyronie disease referred to the urology clinic of Imam Reza Hospital of Kermanshah. 34 eligible people will be selected conveniently. A random table is used for randomization and participants are assigned to two intervention groups.

##### Settings and conduct

This study is a non-blinded clinical trial. The angle of deviation of the penis will be measured using a goniometer in the case of an artificial erection. This study will be performed in the urology clinic of Imam Reza Hospital in Kermanshah.

##### Participants/Inclusion and exclusion criteria

Inclusion criteria: Age between 18 and 65; The duration of the disease is more than 12 months; Diagnosis of pneumonia based on the opinion of a urologist and the presence of palpable plaque; Married patients Exclusion criteria: Patient with calcified plaque; History of penile surgery History of hypo or epispadias; History of intra-plaque injection into the penis; Existence of 2 lesions or lesions with non-measurable shape

##### Intervention groups

In the first intervention group, for patients, verapamil with a dose of 10 mg and diluted in 10 ml of distilled water using a 10 ml syringe and a needle with a 25 gauge will be injected intralesionally twice a week for 12 weeks. In the second intervention group, patients will receive extracorporeal shock wave therapy in the form of 2000 shocks per session with an energy of 0.29 millijoules per square meter using a program of 1 session per week for 12 weeks.

#### Main outcome variables

The amount of pain, Erectile dysfunction

#### General information

##### Reason for update

##### Acronym

##### IRCT registration information

IRCT registration number: **IRCT20130812014333N169**

Registration date: **2021-06-07, 1400/03/17**

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

Last update: **2021-06-07, 1400/03/17**

Update count: **0**

##### Registration date

2021-06-07, 1400/03/17

##### Registrant information

##### Name

Feizollah Foroughi

##### Name of organization / entity

kermanshah University of Medical Sciences

##### Country

Iran (Islamic Republic of)

##### Phone

+98 83 1821 4653

##### Email address

fforoughi@kums.ac.ir

##### Recruitment status

**Recruitment complete**

##### Funding source

##### Expected recruitment start date

2021-06-04, 1400/03/14

##### Expected recruitment end date

2021-12-05, 1400/09/14

##### Actual recruitment start date

empty

**Actual recruitment end date**

empty

**Trial completion date**

empty

**Scientific title**

Comparative study of extracorporeal shock wave therapy (ESWT) and Intra-Plaque Injection of Verapamil in the Treatment of Peyronie's Disease

**Public title**

Comparison of extracorporeal shock wave therapy with Intra-Plaque Injection of Verapamil in the Treatment of Peyronie's Disease

**Purpose**

Treatment

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

Age between 18 and 65 The duration of the disease is more than 12 months Diagnosis of pneumonia based on the opinion of a urologist and the presence of palpable plaque Married patients

**Exclusion criteria:**

Patient with calcified plaque History of penile surgery History of hypo or epispadias History of intra-plaque injection into the penis Existence of 2 lesions or lesions with non-measurable shape

**Age**

From **18 years** old to **65 years** old

**Gender**

Both

**Phase**

2-3

**Groups that have been masked**

*No information*

**Sample size**

Target sample size: **34**

**Randomization (investigator's opinion)**

Randomized

**Randomization description**

Using the random number table, patients are divided into two groups. Each patient is assigned a 4-digit code based on the random number table, Based on the right number of patients code, the patients are divided into two groups. Patients whose last digit is 0, 2, 4, 6, 8 will be assigned to the first intervention group and patients whose last digit is 1,3,5, 7, 9 will be second intervention group

**Blinding (investigator's opinion)**

Not blinded

**Blinding description****Placebo**

Used

**Assignment**

Parallel

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

empty

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

Ethics committee of Kermanshah University of Medical Sciences

**Street address**

Vice Chancellor for Research Affairs, Building No.2, Shahid Beheshti, Kermanshah University of Medical Sciences

**City**

Kermanshah

**Province**

Kermanshah

**Postal code**

6715847141

**Approval date**

2021-04-26, 1400/02/06

**Ethics committee reference number**

ir.kums.rec.1400.107

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

Peyronie's disease

**ICD-10 code**

N48.6

**ICD-10 code description**

Induration penis plastica

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

The amount of pain

**Timepoint**

Beginning of study, end of week 16

**Method of measurement**

Based on Visual Pain Scale (VAS)

**2****Description**

Erectile dysfunction

**Timepoint**

Beginning of study, end of week 16

**Method of measurement**

Based on the Erection Function Questionnaire

**Secondary outcomes**

empty

**Intervention groups**

## 1

### Description

In the first intervention group, for patients, verapamil with a dose of 10 mg and diluted in 10 ml of distilled water using a 10 ml syringe and a needle with a 25 gauge will be injected intralesionally twice a week for 12 weeks.

### Category

Treatment - Drugs

## 2

### Description

In the second intervention group, patients will receive extracorporeal shock wave therapy in the form of 2000 shocks per session with an energy of 0.29 millijoules per square meter using a program of 1 session per week for 12 weeks.

### Category

Treatment - Other

## Recruitment centers

## 1

### Recruitment center

#### Name of recruitment center

Emam Reza Hospital

#### Full name of responsible person

Sajad Moradi

#### Street address

Emam Reza Hospital, Parastar Boulevard

#### City

Kermanshah

#### Province

Kermanshah

#### Postal code

6715847141

#### Phone

+98 83 3427 6306

#### Email

sajad3258985952@gmail.com

## Sponsors / Funding sources

## 1

### Sponsor

#### Name of organization / entity

Kermanshah University of Medical Sciences

#### Full name of responsible person

Dr. Reza Khodarahmi

#### Street address

Vice Chancellor for Research Affairs, Kermanshah University of Medical Sciences, Building No.2, Shahid Beheshti Boulevard

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#### Province

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#### Phone

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#### Email

rkhodarahmi@mbrc.ac.ir

#### Grant name

#### Grant code / Reference number

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

Yes

#### Title of funding source

Kermanshah 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

Kermanshah University of Medical Sciences

#### Full name of responsible person

Sajad Moradi

#### Position

Resident of Urology

#### Latest degree

Medical doctor

#### Other areas of specialty/work

Urology

#### Street address

Emam Reza Hospital, Parastar Boulevard

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#### Province

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## Person responsible for scientific inquiries

### Contact

#### Name of organization / entity

Kermanshah University of Medical Sciences

#### Full name of responsible person

Dr. Hossein Abdi

#### Position

Faculty member of Kermanshah University of Medical Sciences

#### Latest degree

Specialist  
**Other areas of specialty/work**  
Urology  
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## Person responsible for updating data

**Contact**  
**Name of organization / entity**  
Kermanshah University of Medical Sciences  
**Full name of responsible person**  
Sajad Moradi  
**Position**  
Resident of Urology  
**Latest degree**  
Medical doctor  
**Other areas of specialty/work**  
Urology  
**Street address**  
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**City**  
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**Province**  
Kermanshah  
**Postal code**  
6715847141  
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**Email**  
sajad3258985952@gmail.com

## 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 more information

### Study Protocol

No - There is not 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

No - There is not 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

Not applicable

### Data Dictionary

Not applicable