

Clinical Trial Protocol

Iranian Registry of Clinical Trials

17 Sep 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)

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+98 83 1821 4653

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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

AgeFrom **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

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Kermanshah

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6715847141

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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

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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

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

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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
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Person responsible for updating data

Contact
Name of organization / entity
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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 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