

Clinical Trial Protocol

Iranian Registry of Clinical Trials

27 Jul 2026

Comparing the effect of radial extracorporeal shock wave with and without manual penile stretching on Peyronie's disease: A randomized clinical trial

Protocol summary

Study aim

comparing the effect of radial extracorporeal shock wave with and without manual penile stretching on Peyronie's disease.

Design

A controlled, parallel-group, single-blind, randomized clinical trial of 30 patients. Permutation block randomization is used.

Settings and conduct

Study will be conducted at the Neuromuscular Rehabilitation Research Center of Semnan University of Medical Sciences, Men with Peyronie's disease will be treated in either of two intervention or control groups. Using a therapist, the evaluator will be blinded to the type of intervention

Participants/Inclusion and exclusion criteria

Inclusion criteria: age older than 18 years; VAS less than 7 in resting and erection; men with full erection Exclusion criteria: Receiving any medication in last three weeks; inability to tolerate pain during treatment; any surgery or disease in the urinary-genital tract; psychiatric diseases or psychogenic erectile dysfunction; neurological disease and lumbar sacral peripheral nerve damage; penile abnormalities

Intervention groups

The intervention group will receive radial extracorporeal shock wave and manual stretching simultaneously, the skin covering the plaque is locally anesthetized with lidocaine spray. The therapist stretches the head of the penis between the two fingers of one hand to the maximum amount tolerated by the patient and with the other hand applies mechanical pressure to the concavity of the body of the penis. Mechanical pressure of 4 bar with frequency of 8 Hz and 3000 strokes is given in six sessions and twice a week. The control group will receive radial extracorporeal shock wave in the resting state of the penis with the above method.

Main outcome variables

Pain with VAS; length of penis with photography and ruler; angle of penile deviation with photography and goniometer; sexual function with IIEF-5 questionnaire; size of the penile plaque with sonography

General information

Reason for update

Acronym

ESWT(extracorporeal shock wave therapy)

IRCT registration information

IRCT registration number: **IRCT20190108042292N4**

Registration date: **2022-11-29, 1401/09/08**

Registration timing: **prospective**

Last update: **2023-01-21, 1401/11/01**

Update count: **1**

Registration date

2022-11-29, 1401/09/08

Registrant information

Name

Cyrus Taghizadeh Delkhosh

Name of organization / entity

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Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2023-02-20, 1401/12/01

Expected recruitment end date

2024-02-20, 1402/12/01 Actual recruitment start date empty Actual recruitment end date empty Trial completion date empty Scientific title Comparing the effect of radial extracorporeal shock wave with and without manual penile stretching on Peyronie's disease: A randomized clinical trial Public title The effect of radial extracorporeal shock wave therapy on Peyronie's disease Purpose Treatment Inclusion/Exclusion criteria Inclusion criteria: Age range older than 18 years old Pain less than 7 in resting and erection according to VAS Men with full erection Exclusion criteria: Drug treatment in three weeks before the intervention Inability to tolerate pain during radial extracorporeal shock wave treatment Any surgery or disease in the urinary-genital tract Psychiatric diseases or psychogenic erectile dysfunction Neurological disease and lumbar sacral peripheral nerve damage Penile abnormalities. Age From 18 years old Gender Male Phase N/A Groups that have been masked Outcome assessor Sample size Target sample size: 30 Randomization (investigator's opinion) Randomized Randomization description The sample size in each group is 15 people (30 people in total). Permuted block randomization method will be used for randomization. In this regard, blocks of four with numbers 1 to 6 will be used as follows: (in each block, a means the intervention group and b means the control group): 1-aabb 2-abba 3-abab 4-baba 5-baab 6-bbaa After choosing numbers one to six from the table of random numbers (numbers 0 and 7 to 9 are not taken into account), the block associated with each number is determined and the eligible people are enrolled in the study from left to right in each block and will be assigned in one of a or b group. The numbers will be selected seven times and the first 28 people will be grouped in this way, and the last two people will be entered into the group by assigning a coin. Participants, therapists, and evaluators will be unaware of the grouping. To implement the generated random sequence, the method of hiding the box or coded cans is used. In this method,	the cans will be numbered based on a random sequence, and inside the boxes, the desired intervention will be given to the therapist with a sheet on which the random allocation is written, with the condition that the boxes are completely sealed, and the therapist will assign patients to intervention and control groups based on the order of arrival. Blinding (investigator's opinion) Single blinded Blinding description A physiotherapist will be in charge of the treatment process of the intervention group, and another physiotherapist and a radiologist will evaluate the desired variables. Therefore, the future study will be a single-blind study. Placebo Not used Assignment Parallel Other design features Thirty patients participating in this study are placed randomly in two groups. With 15 patients in intervention group who are treated with extracorporeal shock waves in the stretched position of the penis and 15 patients in control group who are treated with radial extracorporeal shock wave treatment in the resting or flaccid state of the penis, six sessions, 2 times a week. Secondary Ids empty Ethics committees 1 Ethics committee Name of ethics committee Research Ethics Committees of Semnan University Of Medical Sciences and Health Services Street address Basj Blvd, Semnan University of Medical Sciences City Semnan Province Semnan Postal code 3514799442 Approval date 2022-10-24, 1401/08/02 Ethics committee reference number IR.SEMUMS.REC.1401.198 Health conditions studied 1 Description of health condition studied Peyronie's disease ICD-10 code N48.6 ICD-10 code description
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Primary outcomes

1

Description

Penile plaque dimensions

Timepoint

Before and After the Intervention and one month follow up

Method of measurement

Size of the penile plaque (length, width, circumference, and surface of the plaque) with ultrasonography will be measured

Secondary outcomes

1

Description

Sexual function, pain, length and angle of penis

Timepoint

Before and After the intervention and one month follow up

Method of measurement

Sexual function with International index of erectile function questionnaire-5 , pain with visual analogue scale, length of the penis with photography and ruler, angle of penile deviation with photography and goniometer will be measured.

Intervention groups

1

Description

Intervention group: The treatment in the intervention group (15 people) will include radial extracorporeal shock wave treatment and manual stretching simultaneously, the skin covering the plaque is locally anesthetized with lidocaine spray. The therapist stretches the head of the penis between the two fingers of one hand to the maximum amount tolerated by the patient and with the other hand applies mechanical pressure to the concavity of the body of the penis. Mechanical pressure of 4 bar with the frequency of 8 Hz and 3000 strokes is given in six sessions and twice a week

Category

Treatment - Devices

2

Description

Control group: The control group (15 people) will receive the radial extracorporeal shock wave treatment in the resting or flaccid state of the penis flaccid with the above method

Category

Treatment - Devices

Recruitment centers

1

Recruitment center

Name of recruitment center

Neuromuscular Rehabilitation Research Center of Semnan University of Medical Sciences

Full name of responsible person

Amin Mottahedi

Street address

Neuromuscular Rehabilitation Research Center, Quds Blvd

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Sponsors / Funding sources

1

Sponsor

Name of organization / entity

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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

Semnan 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

Semnan University of Medical Sciences

Full name of responsible person

Dr. Cyrus Taghizadeh Delkhoush

Position

Associate professor

Latest degree

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Other areas of specialty/work

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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

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