

Clinical Trial Protocol

Iranian Registry of Clinical Trials

10 Jun 2026

Comparison of the therapeutic effect of verapamil and triamcinolone drugs and their simultaneous use with macroneedling in patients with Peyronie's plaque

Protocol summary

Study aim

Determining the therapeutic effect of verapamil and triamcinolone drugs and investigating their simultaneous use with macroneedling in patients with Peyronie's plaque.

Design

The study is conducted as a clinical trial with a control group, with parallel groups, double-blind, randomized, on 60 patients. RNG plugin is used for randomization in excel software.

Settings and conduct

60 eligible patients who were selected from the patients referred to the Shahada Tajrish Hospital clinic in Tehran were randomly assigned to the intervention group or the control group. Standard medical treatment will be given to all patients, as well as the consent form will be explained to all patients about the process of intervention and the complications caused by it. Before the intervention and after the intervention, patients' information including the size of the plaque before and after the treatment, the amount of penile curvature before and after the treatment, the amount of erectile dysfunction before And after the treatment. (IIEF-5), the amount of pain during erection(VAS)is collected.

Participants/Inclusion and exclusion criteria

Entry requirements: Patients with Peyronie's plaque confirmed by ultrasound referring to Tajrish Martyrs Hospital Age 20-65 years Non-entry conditions: Having a history of trauma and fracture of the penis Having a history of previous surgery on the penis Having a history of pelvic radiotherapy

Intervention groups

The intervention is performed by macroneedling and by a needle with a length of 8-10 mm The intervention process includes the injection of verapamil and triamcinolone drugs along with macroneedling technique 6 times a week at the site. In the control group, only

verapamil and triamcinolone injections are performed
Main outcome variables
Erectile dysfunction; Pain; Curvature of the penis

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20230408057854N1**

Registration date: **2023-05-11, 1402/02/21**

Registration timing: **prospective**

Last update: **2023-05-11, 1402/02/21**

Update count: **0**

Registration date

2023-05-11, 1402/02/21

Registrant information

Name

hossein rahnama

Name of organization / entity

Country

Iran (Islamic Republic of)

Phone

+98 56 3282 2705

Email address

drhossein2020@sbmu.ac.ir

Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2023-05-22, 1402/03/01

Expected recruitment end date

2024-05-21, 1403/03/01

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Comparison of the therapeutic effect of verapamil and triamcinolone drugs and their simultaneous use with macroneedling in patients with Peyronie's plaque

Public title

The therapeutic effect of verapamil and triamcinolone along with macroneedling in the treatment of Peyronie's plaque

Purpose

Treatment

Inclusion/Exclusion criteria**Inclusion criteria:**

Suffering from Peyronie's plaque confirmed by ultrasound Age between 20-65 years

Exclusion criteria:

History of trauma and penis fracture History of previous surgery on the penis History of pelvic radiotherapy

Age

From **20 years** old to **65 years** old

Gender

Male

Phase

N/A

Groups that have been masked

- Participant
- Investigator

Sample size

Target sample size: **64**

Randomization (investigator's opinion)

Randomized

Randomization description

First, by using the Random number generation plugin in Excel software, a table of random numbers from 1 to 60 is prepared in a non-sequential and scattered manner, and intervention and control are done by assigning numbers to two groups of 60 people. The randomization process is done by the study methodology consultant, and the clinical researchers do not know about the randomization process, and only randomized codes from 1 to 60 will be provided to them.

Blinding (investigator's opinion)

Double blinded

Blinding description

After selecting the samples, none of the sampled people will know about randomization and the process of allocation to groups. Doctors are given a table of coded numbers in advance and patients are included in the study in the order of the numbers in the table. Therefore, the present study is double-blind. All patients receive routine medical treatment, but the macroneedling technique is performed for the case group, but this procedure is not performed for the control group.

Placebo

Not used

Assignment

Parallel

Other design features**Secondary Ids**

empty

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

Shahid Beheshti University of Medical Sciences Ethics Committee

Street address

Shahid Beheshti University of Medical Sciences, Taleghani Street, Valenjak

City

Tehran

Province

Tehran

Postal code

1989934148

Approval date

2022-11-29, 1401/09/08

Ethics committee reference number

IR.SBMU.MSP.REC.1401.452

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

Peyronie's plaque

ICD-10 code

N48.6

ICD-10 code description

Peyronie's disease

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

Peyronie's Plaque size

Timepoint

6 weeks after the start of treatment

Method of measurement

By Penile ultrasound

Secondary outcomes**1****Description**

The amount of curvature of the penis

Timepoint

6 weeks after the start of treatment

Method of measurement

Objective measurement by ruler

Intervention groups

1

Description

Intervention group: use of macroneedling

Category

Treatment - Other

2

Description

Control group: Treatment with triamcinolone and verapamil

Category

Treatment - Drugs

Recruitment centers

1

Recruitment center

Name of recruitment center

Shohada tajrish hospital

Full name of responsible person

Hossein Rahnama

Street address

Shohada Tajrish Hospital, Shahradari St. Postal code 1989934148

City

Tehran

Province

Tehran

Postal code

۱۹۸۹۹۳۴۱۴۸

Phone

+98 21 2271 8000

Email

rahnama2010@gmail.com

Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Shahid Beheshti University of Medical Sciences

Full name of responsible person

nasrin khateri

Street address

Shohada Tajrish Hospital, Shahradari St. Postal code1989934148

City

Tehran

Province

Tehran

Postal code

۱۹۸۹۹۳۴۱۴۸

Phone

+98 21 2387 2523

Email

rahnama2010@gmail.com

Grant name

Grant code / Reference number

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

Yes

Title of funding source

Shahid Beheshti 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

Shahid Beheshti University of Medical Sciences

Full name of responsible person

Hossein Rahnama

Position

resident

Latest degree

Medical doctor

Other areas of specialty/work

Urology

Street address

Shohada Tajrish Hospital, Shahradari St. Postal code1989934148

City

Tehran

Province

Tehran

Postal code

۱۹۸۹۹۳۴۱۴۸

Phone

+98 21 2271 8002

Email

rahnama2010@gmail.com

Person responsible for scientific inquiries

Contact

Name of organization / entity

Shahid Beheshti University of Medical Sciences

Full name of responsible person

حسین رهنما

Position

Resident

Latest degree

Medical doctor

Other areas of specialty/work

Urology

Street address

Shohada Tajrish Hospital, Shahradari St. Postal

code1989934148

City

Tehran

Province

Tehran

Postal code

۱۹۸۹۹۳۴۱۴۸

Phone

+98 21 2271 8002

Email

rahnama2010@gmail.com

Person responsible for updating data

Contact

Name of organization / entity

Shahid Beheshti University of Medical Sciences

Full name of responsible person

Hossein Rahnama

Position

Resident

Latest degree

Medical doctor

Other areas of specialty/work

Urology

Street address

Shohada Tajrish Hospital, Shahradari St. Postal code1989934148

City

Tehran

Province

Tehran

Postal code

۱۹۸۹۹۳۴۱۴۸

Phone

+98 21 2271 8002

Email

rahnama2010@gmail.com

Sharing plan

Deidentified Individual Participant Data Set (IPD)

Undecided - It is not yet known if there will be a plan to make this available

Study Protocol

Yes - There is a plan to make this available

Statistical Analysis Plan

Yes - There is a plan to make this available

Informed Consent Form

Yes - There is a plan to make this available

Clinical Study Report

Yes - There is a plan to make this available

Analytic Code

Not applicable

Data Dictionary

Not applicable

Title and more details about the data/document

All data is potentially shareable after de-identifying individuals

When the data will become available and for how long

The access period starts immediately after the results are printed

To whom data/document is available

All researchers

Under which criteria data/document could be used

Any use of documents should be done in coordination with the researcher

From where data/document is obtainable

Hossein Rahnama via the email address below rahnama2010@gmail.com

What processes are involved for a request to access data/document

Send an email to the researcher

Comments