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

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Iran (Islamic Republic of)

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+98 56 3282 2705

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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
fter 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
۱۹۸۹۹۳۴۱۴۸
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
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Shohada Tajrish Hospital, Shahradari St. Postal code 1989934148
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Sponsors / Funding sources

1

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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
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
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Hossein Rahnama
Position
resident
Latest degree
Medical doctor
Other areas of specialty/work
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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