

Clinical Trial Protocol

Iranian Registry of Clinical Trials

09 Jun 2026

Assessment of treatment efficacy of Nd-YAG laser beside intra lesion Verapamil injection in Peyronie's Disease patients referring to Shohada-e-Tajrish hospital : a randomized clinical trial

Protocol summary

Summary

The purpose of this study was to determine the effectiveness of adding laser therapy to intraperitoneal injection of verapamil in patients with Peyronie's Disease. Inclusion criteria are all patients with a Peyronie's Disease who were over 18 years of age and had at least 6 months of it. By urologist, they have been clinically examined and measured the size of plaque by ultrasound. Exclusion criteria are patients who have a Peyronie's Disease and receive multiple treatments, a skin disorder in the penis, a history of Skin inflammatory diseases, uncontrolled hypertension. 80 patients with plaque after having informed consent based on Inclusion criteria using simple denture technique with non-transparent envelopes divided into verapamil injections and simultaneous laser treatment group or injecting with silent laser group and According to the protocol, it is treated by a urologist and a specialist in the physical medicine unit and the variables such as plaque size, deviation and pain in sexual activity, sexual satisfaction will be considered one month and three months after treatment. In the treatment group for 6 Weeks, two sessions in a week, 1064 lasers with a power of 0.5 watts and a dose of 50 jules per square centimeter in an area of one square with 1 minute and 40 seconds per session is performed with a BTL-6000 high intensity LASER 12W and a 10 mm probe. Six injections of intraperitoneally injected verapamil with insulin needle will be done weekly. In the control group, only the standard treatment for verapamil injection is performed and the laser probe is placed on the plaque only with red light. Response to treatment will check one month and three months after treatment by measurements of pain, plaque size by ultrasound by a single radiologist, deformity, duration of illness and sexual function based on the size of the plaque and the curvature of the penis, Based on the lateral image of the penis and using the Photoshop

software.

General information

Acronym

IRCT registration information

IRCT registration number: **IRCT201710088146N27**

Registration date: **2017-10-13, 1396/07/21**

Registration timing: **registered_while_recruiting**

Last update:

Update count: **0**

Registration date

2017-10-13, 1396/07/21

Registrant information

Name

Mohammadreza Razaghi

Name of organization / entity

Laser application in medical sciences research center

Country

Iran (Islamic Republic of)

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+98 21 2271 8021

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Recruitment status

Recruitment complete

Funding source

Shahid Beheshti University of Medical Sciences

Expected recruitment start date

2017-09-23, 1396/07/01

Expected recruitment end date

2018-02-20, 1396/12/01

Actual recruitment start date

empty

Actual recruitment end date

empty
Trial completion date
empty

Scientific title
Assessment of treatment efficacy of Nd-YAG laser beside intra lesion Verapamil injection in Peyronie's Disease patients referring to Shohada-e-Tajrish hospital : a randomized clinical trial

Public title
Efficacy of Nd-YAG Laser with Verapamil in Peyronie's Disease

Purpose
Treatment

Inclusion/Exclusion criteria
Inclusion Criteria: All Patients with Peyronie's Disease; aged 18 years and over; have at least Peyronie's Disease for 6 months ; Exclusion criteria: Patients with a Peyronie's Disease and receive multiple treatments; Skin disorder in the penis; History of Inflammatory diseases of the skin; uncontrolled hypertension; history of heart attacks in the last one month; patients with acute phase or released fibrosis plaque during the penis; patients who are not satisfied to entering the study;

Age
From **18 years** old

Gender
Male

Phase
N/A

Groups that have been masked
No information

Sample size
Target sample size: **80**

Randomization (investigator's opinion)
Randomized

Randomization description

Blinding (investigator's opinion)
Single blinded

Blinding description

Placebo
Used

Assignment
Parallel

Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee
Organizational committee of ethics in biomedical research Shahid Beheshti University of Medical Scie

Street address
Next to Ayatollah Taleghani Hospital, Shahid Arabi ST. Yemen street, Shahid Chamran highway, Tehran

City
Tehran
Postal code
Approval date
2017-08-06, 1396/05/15
Ethics committee reference number
IR.SBMU.RETECH.REC.1396.285

Health conditions studied

1

Description of health condition studied

Peyronie's Disease

ICD-10 code

N48.6

ICD-10 code description

Induratio penis plastica

Primary outcomes

1

Description

Plaque size

Timepoint

One month and three months after the end of treatment

Method of measurement

sonography

Secondary outcomes

empty

Intervention groups

1

Description

Intervention group: In the treatment group for 6 weeks , two sessions in a week, 1064 laser with a power of 0.5 watts and a dose of 50 jules per square centimeter in an area of 1 centimeter square with a time of 1 minute and 40 seconds per session with a BTL-6000 high intensity LASER 12W, and 10mm probe, and 6 injections of verapamil intra-lesion with insulin needle will be performed weekly.

Category

Treatment - Other

2

Description

Control group: The only standard treatment for verapamil injection is done and the laser probe is placed on the plaque with red light only.

Category

Placebo

Recruitment centers

1

Recruitment center

Name of recruitment center

Laser Application Research Center in Medical Sciences

Full name of responsible person

Dr.Farzad Allameh

Street address

Shohadaye Tajrish Hospital, Tajrish, Tehran

City

Tehran

Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Vice chancellor for research, Shahid Beheshti University of Medical Sciences

Full name of responsible person

Dr Afshin Zarghi

Street address

Next to Ayatollah Taleghani Hospital, Shahid Arabi ST. Yemen street, Shahid Chamran highway, Tehran

City

Tehran

Grant name

Grant code / Reference number

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

Yes

Title of funding source

Vice chancellor for research, Shahid Beheshti University of Medical Sciences

Proportion provided by this source

100

Public or private sector

empty

Domestic or foreign origin

empty

Category of foreign source of funding

empty

Country of origin

Type of organization providing the funding

empty

Person responsible for general inquiries

Contact

Name of organization / entity

Laser Application Research Center in Medical Science

Full name of responsible person

Dr.Farzad Allameh

Position

urologist

Other areas of specialty/work

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Person responsible for updating data

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Name of organization / entity

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Web page address

Sharing plan

Deidentified Individual Participant Data Set (IPD)

empty

Study Protocol

empty

Statistical Analysis Plan

empty
Informed Consent Form
empty
Clinical Study Report
empty

Analytic Code
empty
Data Dictionary
empty