

Clinical Trial Protocol

Iranian Registry of Clinical Trials

16 Sep 2026

A comparative investigation of therapeutic effect ND yag laser on small vascular lesions on the lower limbs with energy of 160-180 and pulse duration of 50 with respect to energy 120-140 and pulse duration 10

Protocol summary

Study aim

Using the results of this study, we can help treat lower limb vascular lesions with ND yag laser.

Design

A clinical trial with a control group, with parallel groups, double-blind (patient, analyzer and evaluator) as a computer block randomized by SPSS software and phase 2 is performed on 37 patients. In this way, if both lower limbs are involved, one limb is randomly lasered with an energy of 160-180 and a pulse of 50 and the other limb with an energy of 120-140 and a pulse of 10. But if only one limb is involved, based on the medial and lateral of that limb, the mentioned energy and pulse are given randomly.

Settings and conduct

The first session is patient selection and sono Doppler and then the first laser session(Randomly energy 120-140 and pulse 10 versus energy 160-180 and pulse 50) Second session (2 months later) Evaluate the response and perform the second laser session(same energy and pulse of their first session) Third session (2 months later second session) Final evaluation(Based on response to treatment) Location: Razi Hospital Laser Clinic Double-blind RCT (patient, statistical analyzer, assessor)

Participants/Inclusion and exclusion criteria

37patients Inclusion: Having a vascular lesions both above and below the knee; signing an inform consent; vascular lesions smaller than 3 mm. Exclusion: Having a history of arterial and venous thrombosis; active infection on the area of laser; history of liver cirrhosis or consumption of ocp; vascular lesion only on one side of the knee; history of laser or sclerotherapy during the past 6 months; Pregnancy; skin types 5 and 6; history of sunburn; lactation.

Intervention groups

Patients with small vascular lesions of lower limb

referred to the laser clinic of Razi Hospital in Tehran
1400-1401

Main outcome variables

Age; sex; family history; skin type; location; size

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20211203053262N1**

Registration date: **2022-09-19, 1401/06/28**

Registration timing: **registered_while_recruiting**

Last update: **2022-09-19, 1401/06/28**

Update count: **0**

Registration date

2022-09-19, 1401/06/28

Registrant information

Name

Ehsan Rostami

Name of organization / entity

Country

Iran (Islamic Republic of)

Phone

+98 21 7716 4487

Email address

www.esirost65@yahoo.com

Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2022-06-04, 1401/03/14

Expected recruitment end date

2022-10-06, 1401/07/14

Actual recruitment start date

empty

Actual recruitment end date
empty

Trial completion date
empty

Scientific title
A comparative investigation of therapeutic effect ND yag laser on small vascular lesions on the lower limbs with energy of 160-180 and pulse duration of 50 with respect to energy 120-140 and pulse duration 10

Public title
Evaluation of the effectiveness of ND yag laser on small vascular lesions on lower limb with different energy and pulse duration

Purpose
Treatment

Inclusion/Exclusion criteria
Inclusion criteria:
Intact perforating & deep vessels in ultrasound No active infection of the laser area signing an inform consent No history of arterial & venous thrombosis of the lower extremities The Presence of vascular lesions <3 mm having a vascular lesion both above and below the knee No history of liver cirrhosis No history of laser and sclerotherapy in the area in the last 6 months No history of sunburn No consumption ocp
Exclusion criteria:

Age
No age limit

Gender
Both

Phase
N/A

Groups that have been masked

- Participant
- Outcome assessor
- Data analyser

Sample size
Target sample size: 37

Randomization (investigator's opinion)
Randomized

Randomization description
Randomization method: Blocks 4, 6 and 8, in which there are equal numbers of each group in each block, are used to create a balance in the number of assigned samples of each of the studied groups. Randomization unit: Cluster. For this purpose, people are clustered in groups, then sampled from clusters, and it is used when it is possible to select a group of people and it is easier than selecting people in one The community is defined. We do not have random layering. Randomization tool: statistical software SAS(Statistical Analysis System) Random allocation concealment prevents the disclosure of a random sequence so that the assigned group is not specified prior to the individual allocation. This study is two-blind (patient, assessor, statistical analyzer).

Blinding (investigator's opinion)
Double blinded

Blinding description

Double blind: Participant, Data analyzer, Assessor The participant will not be informed of the result of the assessor and statistical analyzer during the study. The analyzer does not know how to divide the two groups and the type of treatment. The assessor does not know how to divide the two groups and the type of treatment.

Placebo
Not used

Assignment
Parallel

Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee

Ethics committee of Tehran University of Medical Sciences

Street address

No. 533, Razi Dermatology Hospital, Vahdat Islami St., Tehran town

City

Tehran

Province

Tehran

Postal code

1199663911

Approval date

2021-01-25, 1399/11/06

Ethics committee reference number

IR.TUMS.MEDICINE.REC.1399.1073

Health conditions studied

1

Description of health condition studied

lower limb vascular lesions

ICD-10 code

ICD-10 code description

Primary outcomes

1

Description

Vascular lesions recovery rate

Timepoint

Before laser onset, 2 months later, 4 months after initial examination

Method of measurement

Caliper, photography

Secondary outcomes

1

Description

1. Help improve superficial varicose veins and prevent them from becoming deep varicose veins 2. Giving a better appearance to patient's feet 3. Reduce patient anxiety and improve quality of life

Timepoint

Onset, 2 months later, 4 months later

Method of measurement

Photography, caliper

Intervention groups

1

Description

Intervention group: Vascular lesions of less than 3 mm of the lower limb are treated by laser ND yag with energy 160-180 and pulse duration 50 during 0&2 months .

Category

Treatment - Other

2

Description

Control group: Vascular lesions of less than 3mm of the lower limb are treated by laser ND yag with energy 120-140 and pulse duration 10 during 0 & 2 months.

Category

Treatment - Other

Recruitment centers

1

Recruitment center

Name of recruitment center

Razi hospital

Full name of responsible person

Ehsan Rostami

Street address

No 17, Abadi street, north Nabard, Piroozi, Tehran town

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1766637531

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Email

EsiRost65@yahoo.com

Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Tehran University of Medical Sciences

Full name of responsible person

Razi hospital Laser Center

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No. 533, Razi Dermatology Hospital, Vahdat Islami St., Tehran town

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razihospital@sina.tums.ac.ir

Grant name

Grant code / Reference number

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

Yes

Title of funding source

Tehran University of Medical Sciences

Proportion provided by this source

50

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

Tehran University of Medical Sciences

Full name of responsible person

Ehsan Rostami

Position

Resident

Latest degree

Medical doctor

Other areas of specialty/work

Dermatology

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Person responsible for scientific inquiries

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Full name of responsible person

Ehsan Rostami

Position

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Person responsible for updating data

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Sharing plan

Deidentified Individual Participant Data Set (IPD)

Yes - There is 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

No - There is not a plan to make this available

Clinical Study Report

Yes - There is 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

Title and more details about the data/document

All patient information can be shared without mentioning the name.

When the data will become available and for how long

From 6 months after the end of the study until forever

To whom data/document is available

Researchers, experts in the field of laser industry and Dermatologists

Under which criteria data/document could be used

For scientific studies and therapeutic applications

From where data/document is obtainable

medical University Tehran

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

By sending an email to Tehran university of Medical sciences and after reviewing the action is done

Comments