

Clinical Trial Protocol

Iranian Registry of Clinical Trials

24 Jul 2026

Efficacy and side effects of Endovenous laser treatment for uncomplicated varicose veins: a randomized comparative study

Protocol summary

laser.cntr@sbmu.ac.ir

Summary

study will be in shohayae-tajrish hospital.the duration of study will be 18 mounts and patients will be follow up for 18 months.all patients with inclusion criteria after initial physical exams will enter to 2 groups (laser group or open surgery) 65 patients ELVT group and 35HLS group are going to treat with a 980-nm laser diode under local anesthesia. CEAP classification (Clinical Severity, Etiology, Anatomy, Pathophysiology) and AVSS scores (Aberdeen Varicose Vein Symptom Severity Score) are used to determine disease severity and symptoms before and after the procedure. Outcome will be measure by the rate of recurrence as will be show in Doppler ultrasonography evaluation.

Recruitment status

Recruitment complete

Funding source

Shahid Beheshti University of Medical Sciences

Expected recruitment start date

2012-12-21, 1391/10/01

Expected recruitment end date

2016-01-20, 1394/10/30

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

General information

Acronym

IRCT registration information

IRCT registration number: **IRCT201301118146N5**

Registration date: **2013-01-26, 1391/11/07**

Registration timing: **registered_while_recruiting**

Last update:

Update count: **0**

Registration date

2013-01-26, 1391/11/07

Registrant information

Name

Mohammadreza Razaghi

Name of organization / entity

Laser application in medical sciences research center

Country

Iran (Islamic Republic of)

Phone

+98 21 2271 8021

Email address

Scientific title

Efficacy and side effects of Endovenous laser treatment for uncomplicated varicose veins: a randomized comparative study

Public title

Efficacy of laser in varicose insufficiency

Purpose

Treatment

Inclusion/Exclusion criteria

Inclusion criteria: age 18 to 65 years; insufficiency of GSV and the Saphenofemoral junction (SFJ) with reflux at least up to the knee and symptoms of GSV insufficiency or CVI. Exclusion criteria: pregnancy; active malignancy; arterial occlusive disease with an Ankle Brachial Index of below 0.8; acute deep vein thrombosis (DVT); thrombophilia or high risk of pulmonary thromboemboli; history of inguinal surgery except for hernia and insufficiency of the lesser saphenous vein in the same limb requiring treatment. aim :compare Efficacy and side effects of Endovenous laser treatment for uncomplicated varicose vein

Age

From **18 years** old to **65 years** old

Gender

Both

Phase

N/A

Groups that have been masked

No information

Sample size

Target sample size: 65

Randomization (investigator's opinion)

Randomized

Randomization description**Blinding (investigator's opinion)**

Not blinded

Blinding description**Placebo**

Not used

Assignment

Parallel

Other design features**Secondary Ids**

empty

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

shahid beheshti ethics committee

Street address

shahid beheshti medical university

City

tehran

Postal code**Approval date**

2009-06-21, 1388/03/31

Ethics committee reference number

69

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

Varicose veins of lower extremities

ICD-10 code

183

ICD-10 code description

183.9

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

patency rate

Timepoint

6months-12 month- 18 month

Method of measurement

Doppler Ultrasonography

2**Description**

CEAP score

Timepoint

before treatment- 3 week-6 month-12 month-18 month

Method of measurement

physical exam

3**Description**

AVVSS score

Timepoint

Before treatment -1week 3 month-6 month-12 month-18 month

Method of measurement

physical exam

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

pain

Timepoint

before treatment-1 week-3 month-6 month-12 month-18 month

Method of measurement

physical exam

2**Description**

edema

Timepoint

before treatment--1 week-3 month-6 month-12 month-18 month

Method of measurement

physical exam

3**Description**

pigmentation

Timepoint

before treatment -1 week- 3 month-6 month- 12 month-18 month

Method of measurement

physical exam

Intervention groups**1****Description**

laser ablation of saphenofemoral junction in varicose patient

Category

Treatment - Surgery

2

Description

high ligation of saphenofemoral junction by surgical technique

Category

Treatment - Surgery

Recruitment centers

1

Recruitment center

Name of recruitment center

Shohadaye Tajrish Hospital

Full name of responsible person

Street address

City

Tehran

Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Shahid Beheshti University of Medical Sciences-
Research & Technology Affairs

Full name of responsible person

hosein godarzy

Street address

chamran highway-yaman street,parvaneh
street,beside taleghany hospital,Shahid Beheshti
University of Medical Sciences, Tehran, Iran-building
no. 2-first floor--

City

Tehran

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-Research
& Technology Affairs

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

Shahid Beheshti University of Medical Sciences

Full name of responsible person

Khashayar Atqiaee

Position

MD, resident of Surgery

Other areas of specialty/work

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vascular surgen

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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