Clinical Trial Protocol
Iranian Registry of Clinical Trials

17 Sep 2026

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

Protocol summary

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.

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
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Iran (Islamic Republic of)
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laser.cntr@sbmu.ac.ir

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

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
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Person responsible for scientific inquiries

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Person responsible for updating data

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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