

Clinical Trial Protocol

Iranian Registry of Clinical Trials

17 Sep 2026

Comparison of the effectiveness of Radio-frequency Ablation with Endovenous Laser Ablation of lower limb varicosis, A randomized controlled trial

Protocol summary

Study aim

The aim of this study was to compare the clinical results and complications of two new methods of varicose vein treatment

Design

Two arm parallel group single-blind randomized trial, on 1090 patients. The rand function of Excel software (random table) is used for randomization.

Settings and conduct

All patients referred to the Varice Clinic located in Tehran, Iran undergo Doppler ultrasound and if they have inclusion criteria and no exclusion criteria, they will be included in the study. Patients are divided into two groups based on a random number table. In the first group, laser treatment is performed and in the second method, radiofrequency method is performed. Because all preoperative procedures are the same for patients and only the device used in the operating room is different, the patient is not informed of the method used and becomes blind.

Participants/Inclusion and exclusion criteria

All patients aged 18-65 years referred to the Varice Clinic who consider color Doppler ultrasound of saphenous vein insufficiency and reflux of sapheno-femoral junction and are candidates for endovenous treatment are included in the study. Recurrent cases, impossible to follow-up patients, pregnant women, people with active cancer, lower extremity arterial disease, active DVT, thrombophilia, people at high risk for pulmonary embolism and a history of inguinal surgery other than hernias are excluded.

Intervention groups

In the first group, patients are treated with endovenous laser for ablation of varicose veins after transfer to the operating room and local anesthesia, and in the second group, this treatment is using a radio frequency (RF) ablation device.

Main outcome variables

Duration of surgery; Intraoperative and postoperative pain; Pain in the third week, third, sixth and twelfth months; Complications of surgery; Recurrence of varicose veins, CEAP stage , AVVSS score

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20200404046936N4**
Registration date: **2020-11-01, 1399/08/11**
Registration timing: **prospective**

Last update: **2020-11-01, 1399/08/11**

Update count: **0**

Registration date

2020-11-01, 1399/08/11

Registrant information

Name

Arash Mohammadi Tofigh

Name of organization / entity

Country

Iran (Islamic Republic of)

Phone

+98 21 7758 5851

Email address

arash_mtofigh@yahoo.com

Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2020-12-21, 1399/10/01

Expected recruitment end date

2021-07-22, 1400/04/31

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Comparison of the effectiveness of Radio-frequency Ablation with Endovenous Laser Ablation of lower limb varicosis, A randomized controlled trial

Public title

RF ablation vs EVLA in lower limb varicosis

Purpose

Treatment

Inclusion/Exclusion criteria**Inclusion criteria:**

Abnormal greater saphenous vein Doppler and saphenofemoral reflux Candidates for endovenous intervention

Exclusion criteria:

Recurrent cases Impossible to follow-up Pregnancy Active malignancy Arterial occlusive disease Known DVT Known thrombophilia High risk for Thromboembolism History of inguinal surgery except for hernia

Age

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

Gender

Both

Phase

N/A

Groups that have been masked

- Participant

Sample size

Target sample size: **1090**

Randomization (investigator's opinion)

Randomized

Randomization description

Simple individual randomization using a table of random numbers

Blinding (investigator's opinion)

Single blinded

Blinding description

Patients are not aware of the method used to treat them (laser or radiofrequency)

Placebo

Not used

Assignment

Parallel

Other design features**Secondary Ids**

empty

Ethics committees**1**

Ethics committee

Name of ethics committee

Ethics committee of national institute for health research

Street address

Shahid Madani st, Imam Hossein Medical Center

City

tehran

Province

Tehran

Postal code

1617763141

Approval date

2018-04-10, 1397/01/21

Ethics committee reference number

IR.TUMS.NIHR.REC.1397.016

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

Lower limb varicosis

ICD-10 code**ICD-10 code description****Primary outcomes****1****Description**

duration of intervention

Timepoint

during the intervention

Method of measurement

Record start and end time

2**Description**

Pain

Timepoint

During surgery; 8 hours and 24 hours after the intervention; 7 days: 3 months, 6 and 12 months after the intervention

Method of measurement

numerical rating scale (NRS)

3**Description**

the clinical, etiologic, anatomic, and pathologic (CEAP) stage

Timepoint

Before the intervention; 7 days: 3 months, 6 and 12 months after intervention

Method of measurement

CEAP questionnaire

4**Description**

Recurrence

Timepoint

7 days; 3 months 6 and 12 months after intervention

Method of measurement

Ultrasonography set

Secondary outcomes

empty

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

Intervention group: Radiofrequency varicose vein treatment group in which Covidien radiofrequency device and ClosureFast fiber are used for intravascular treatment of varicose veins

Category

Treatment - Surgery

2**Description**

Control group: Laser treatment of varicose veins in which a 980 nm diode laser device and 600 micron fiber are used

Category

Treatment - Surgery

Recruitment centers**1****Recruitment center****Name of recruitment center**

Imam Hossein Medical Center

Full name of responsible person

Arash Mohammadi Tofigh

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Web page address**Sponsors / Funding sources****1****Sponsor****Name of organization / entity**

Shahid Beheshti University of Medical Sciences

Full name of responsible person

Afshin Zarghi

Street address

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Province

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1985717443

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+98 21 23871

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info@sbmu.ac.ir

Web page address**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

2**Sponsor****Grant name****Grant code / Reference number****Is the source of funding the same sponsor organization/entity?**

empty

Title of funding source**Proportion provided by this source****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

Arash Mohammadi Tofigh

Position

Associate Professor

Latest degree

Specialist
Other areas of specialty/work
General Surgery
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Person responsible for scientific inquiries

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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

Yes - There is 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 data is potentially shareable after unidentified individuals

When the data will become available and for how long

Access period starts 6 months after the results are published

To whom data/document is available

Researchers working in academic and scientific institutions

Under which criteria data/document could be used

Any request for specific use of the results must be referred to the author

From where data/document is obtainable

arash_mtofigh@yahoo.com

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

The request will be answered immediately upon receipt

Comments