

Clinical Trial Protocol

Iranian Registry of Clinical Trials

18 Sep 2026

Thermal ablation versus foam sclerotherapy for treatment of small saphenous vein

Protocol summary

Study aim

Our aim in this study is to investigate and compare the success rate in the closure of the small saphenous vein reflux in these two methods and also to investigate the complications (such as infection, thrombophlebitis, deep vein thrombosis, pulmonary embolism, bleeding, hyperpigmentation, improving the quality of life).

Design

The study is a clinical trial with parallel groups. The patients are selected from those with varicosis insufficiency of small saphenous veins. 50 patients with inclusion criteria are selected through the available sampling method then they are divided into one of two groups foam sclerotherapy and radiofrequency ablation randomly by using a random number table. The trial phase is not applied in this study. The intervention groups are parallel and there is no possibility of blinding.

Settings and conduct

The goal of this study is the comparison of two type modality in varicose vein treatment in Tehran City. 50 patients in two groups are treated with radiofrequency ablation and foam sclerotherapy. In group 1 radiofrequency ablation is performed by thermal ablation of the small saphenous vein. In group 2 the foam sclerotherapy is performed by chemical ablation of the small saphenous vein. In the end, these two groups are compared based on the results of the treatment.

Participants/Inclusion and exclusion criteria

Inclusion criteria: informed consent of patient patients with primary varicosis following insufficiency of small saphenous vein Exclusion criteria: failure to collaborate for follow up

Intervention groups

In this study, the patients are divided into two groups: Group 1: treated with foam sclerotherapy which is chemical ablation of endothelium Group 2: treated with radiofrequency ablation which is thermal ablation of the endothelium.

Main outcome variables

The rate of disease recurrence, The quality of life, deep vein thrombosis, infection

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20230721058865N1**

Registration date: **2023-08-05, 1402/05/14**

Registration timing: **prospective**

Last update: **2023-08-05, 1402/05/14**

Update count: **0**

Registration date

2023-08-05, 1402/05/14

Registrant information

Name

Razieh Niazkeykha

Name of organization / entity

Country

Iran (Islamic Republic of)

Phone

+98 21 8802 9256

Email address

niazkeykha.r@gmail.com

Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2023-08-23, 1402/06/01

Expected recruitment end date

2024-09-22, 1403/07/01

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Thermal ablation versus foam sclerotherapy for treatment of small saphenous vein

Public title

Comparative study of radiofrequency ablation & foam sclerotherapy for treatment patients suffering from varicose veins

Purpose

Treatment

Inclusion/Exclusion criteria**Inclusion criteria:**

Conscious patient consent to enter the study; patients who have 18 years old and suffering from lesser saphenous varicose veins.

Exclusion criteria:

Failure to collaborate for follow-up

Age

From **18 years** old

Gender

Both

Phase

N/A

Groups that have been masked

No information

Sample size

Target sample size: **50**

Randomization (investigator's opinion)

Randomized

Randomization description

A simple randomization method is used, in which the randomization unit is individual, and random sequence generation software (Random Number Generator software) is used. For concealment, non-transparent sealed envelopes with a random sequence are used. In this method, each random number created is recorded on a card and the cards are placed inside the envelopes in order. To maintain the random sequence of the envelopes on the outer surface, the numbering is done in the same order. Finally, the lids of the envelopes are glued and placed in a box. At the time of registration of the participants, based on the order of entry of the eligible participants into the study, one of the envelopes will be opened and the allocated group of that participant will be revealed.

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**

Ethics Committee of Tehran University of Medical Sciences

Street address

North Kargar, Amirabad, Tehran heart center, The rate of disease recurrence, The quality of life, deep vein thrombosis, infection

City

Tehran

Province

Tehran

Postal code

13138-14117

Approval date

2023-07-19, 1402/04/28

Ethics committee reference number

IR.TUMS.THC.REC.1402.041

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

Small saphenous vein reflux

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

Recurrence of Varicose Veins

Timepoint

six weeks after treatment

Method of measurement

Color Doppler Ultrasonography

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

Quality of life

Timepoint

Before and a week after treatment

Method of measurement

SF-12 questionnaire

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

Intervention group: Interventional Group 1: This group was treated with radiofrequency ablation. Treatment

includes segmental thermal ablation of a small saphenous vein through a catheter by a seven-centimeters element. In each segment, the temperature remains at about 120 degrees centigrade for 20 seconds.

Category

Treatment - Devices

2

Description

Intervention group: Intervention group 2 (Foam sclerotherapy): This group will be treated with Foam sclerotherapy. The foam was injected into the vein Under ultrasound guidance. It causes ablation in the vein Endothelium by chemical inflammation.

Category

Treatment - Devices

Recruitment centers

1

Recruitment center

Name of recruitment center

Tehran Heart Center

Full name of responsible person

Raziyeh Niazkeykha

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Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Tehran University of Medical Sciences

Full name of responsible person

Dr. Haleh Ashraf

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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

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

Person responsible for general inquiries

Contact

Name of organization / entity

Tehran University of Medical Sciences

Full name of responsible person

Raziyeh Niazkeykha

Position

Resident

Latest degree

Medical doctor

Other areas of specialty/work

Cardiology

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Person responsible for scientific inquiries

Contact

Name of organization / entity

Tehran University of Medical Sciences

Full name of responsible person

Dr. Yaser Jenab

Position

Associate profesor

Latest degree

Subspecialist

Other areas of specialty/work

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Person responsible for updating data

Contact

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Tehran University of Medical Sciences
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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

Yes - There is a plan to make this available

Data Dictionary

Yes - There is a plan to make this available

Title and more details about the data/document

In the case of the participant's data file, three months after the publication of the article and after the un-identification of the persons, the request can be sent by email.

When the data will become available and for how long

Three months after the publication of the article, upon request, by email, there is a possibility to post.

To whom data/document is available

Only scholars working in academic and scientific institutions

Under which criteria data/document could be used

The name of the first author of the study is required in an extracted article from the study data. In this case, it is possible to perform any statistical analysis.

From where data/document is obtainable

Correspondence by e-mail with the Doctor Yaser Jenab
yasjenab@gmail.com

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

Up to one week after receipt of the email, the requested documentation is sent.

Comments