

Clinical Trial Protocol

Iranian Registry of Clinical Trials

14 Jul 2026

Comparative study of radiofrequency ablation & foam sclerotherapy for treatment patients suffering from great saphenous varicose vein

Protocol summary

Study aim

The measurement of the rate of recurrence, the period of return to daily activities, the rate of pain relief, the cost of spent , and the quality of life improvement in the two groups under treatment by foam sclerotherapy and radiofrequency ablation.

Design

The study is a clinical trial with parallel groups. The patients are selected from those with varicosis secondary to primary insufficiency of great saphenous vein. 60 patients with inclusion criteria are selected through available sampling method then they are divided in one of two groups foam sclerotherapy and radiofrequency ablation randomly by using 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 Kermanshah City. 60 patients in two groups are treated with radiofrequency ablation and foam sclerotherapy. In group 1 radiofrequency ablation is performed by thermal ablation of the great saphenous vein . In group 2 the foam sclerotherapy is performed by chemical ablation of the great saphenous vein. At the end, these two groups are compared based on results of the treatment.

Participants/Inclusion and exclusion criteria

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

Intervention groups

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

Main outcome variables

The rate of disease recurrence The recovery time The cost of spent The quality of life The compression of pain

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20180223038837N1**

Registration date: **2018-12-08, 1397/09/17**

Registration timing: **registered_while_recruiting**

Last update: **2018-12-08, 1397/09/17**

Update count: **0**

Registration date

2018-12-08, 1397/09/17

Registrant information

Name

Mohammad Reza Sobhiyeh

Name of organization / entity

Country

Iran (Islamic Republic of)

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Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2018-10-23, 1397/08/01

Expected recruitment end date

2019-05-21, 1398/02/31

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Comparative study of radiofrequency ablation & foam sclerotherapy for treatment patients suffering from great saphenous varicose 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 The patient suffers from great saphenous varicose vein No history of varicose vein The diameter of the great saphenous vein at 3 cm below the saphenophemoral junction in Doppler sonography is between 10 to 20 mm. No duplication of varicose vein Non-use of anti-coagulans and antiplatelet drugs No history of vascular insufficiency

Exclusion criteria:

Failure to collaborate for follow-up

Age

From **18 years** old to **75 years** old

Gender

Both

Phase

N/A

Groups that have been masked

No information

Sample size

Target sample size: **60**

Randomization (investigator's opinion)

Randomized

Randomization description

A total of 60 patients with entering criteria were selected by available sampling. Then, randomly using a random number table, they are placed in one of two groups of foam sclerotherapy and RFA

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 Kermanshah University of

Medical Sciences

Street address

Imam Reza Hospital, Parastar Blvd

City

Kermanshah

Province

Kermanshah

Postal code

671441533

Approval date

2018-09-23, 1397/07/01

Ethics committee reference number

IR.KUMS.REC.1397.493

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

Varicose veins of lower extremities

ICD-10 code

I83

ICD-10 code description

Varicose veins of lower extremities

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

Recurrence of Varicose Veins

Timepoint

One week, one month, three months, six months and 12 months 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-36 questionnaire

2**Description**

Intensity of pain

Timepoint

Before and a week after treatment

Method of measurement

Visual Analogue Scale

3**Description**

Condition of Varicose veins

Timepoint

Before and a week after treatment
Method of measurement
Aberdeen Varicose Veins Questionnaire

4

Description
The interval between the treatment process and the return to usual life
Timepoint
after treatment
Method of measurement
The patient is asked

5

Description
The cost of treatment
Timepoint
After treatment
Method of measurement
Documentation file

Intervention groups

1

Description
Interventional Group 1: This group treated with radiofrequency ablation .Treatment includes segmental thermal ablation of great saphenous vein through a catheter by seven-centimeters element . thermal ablation started two centemeters of below the saphenofemoral junction. In each segment, temperature remains at about 120 degree centegrades for 20 seconds. In this project used radiofrequency catheter for Covidian brand, made in Costa Rica, to do ablation.
Category
Treatment - Devices

2

Description
Intervention group 2(Foam sclerotherapy): This group will be treated with Foam sclerotherapy . Foam includes fibro vein with air with a ratio of one- fifth (with Tesari Method) is mixed and injected into the vein Under ultrasound guidance. It continues as long as the foam reaches of two centimeter of saphenofemoral junction and causes ablation in the vein Endothelium by chemical inflammation. In this project, Sclerosing substance of fibro vein brand, made in England , is used for foam sclerotherapy.
Category
Treatment - Devices

Recruitment centers

1

Recruitment center
Name of recruitment center

Imam Reza Hospital
Full name of responsible person
Mohammadreza Sobhie
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Sponsors / Funding sources

1

Sponsor
Name of organization / entity
Kermanshah University of Medical Sciences
Full name of responsible person
Farid Najafi
Street address
Administrative building of Kermanshah University of Medical Sciences, Shahid Beheshti Blvd., Kermanshah City, Iran
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Email
Farid_n32@yahoo.com
Web page address
<http://vc-research.kums.ac.ir/>
Grant name
Grant code / Reference number
Is the source of funding the same sponsor organization/entity?
Yes
Title of funding source
Kermanshah 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

Kermanshah University of Medical Sciences

Full name of responsible person

Mohammad Reza Sobhiyeh

Position

Assistant Professor

Latest degree

Subspecialist

Other areas of specialty/work

General Surgery

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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 unidentification 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 Mohammadreza Sobhiyeh. Email: mrreza.sobhiyeh@yahoo.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