Clinical Trial Protocol
Iranian Registry of Clinical Trials

17 Sep 2026

Comparative study of radiofrequency ablation & foam sclerothrapy 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 sclerotheraphy 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)

Phone

+98 83 3427 6333

Email address

mohammadreza.sobhieh@kums.ac.ir

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 sclerothrapy 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 Analoge 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 fibrovein 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 fibrovein 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 Sobhieh

Street address

Parastar Blvd

City

Kermanshah

Province

Kermanshah

Postal code

671441533

Phone

+98 83 3427 6301

Email

admin@irhk.ir

Web page address

http://www.irhk.ir

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

City

Kermanshah

Province

Kermanshah

Postal code

671441533

Phone

+98 83 3837 0541

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

Street address
Imam Reza Hospital., Parastar Blvd.

City
Kermanshah

Province
Kermanshah

Postal code
671441533

Phone
+98 83 3427 6333

Fax

Email
mreza.sobhiyeh@yahoo.com

Person responsible for scientific inquiries

Contact

Name of organization / entity
Kermanshah University of Medical Sciences

Full name of responsible person
Mohammad Reza Sobhiyeh

Position
Assistant Professor

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Other areas of specialty/work
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Street address
Imam reza hospital-parastar Ave-kermanshah

City
Kermanshah

Province
Kermanshah

Postal code
671441533

Phone
+98 83 3427 6333

Fax

Email
mreza.sobhiyeh@yahoo.com

Person responsible for updating data

Contact

Name of organization / entity
Kermanshah University of Medical Sciences

Full name of responsible person
Mohammad Reza Sobhiyeh

Position
Assistant Professor

Latest degree
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Other areas of specialty/work
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Imam reza hospital-parastar Ave-kermanshah

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Province
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Postal code
671441533

Phone
+98 83 3427 6333

Fax

Email
mreza.sobhiyeh@yahoo.com

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: mreza.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