Clinical Trial Protocol
Iranian Registry of Clinical Trials

24 Jul 2026

Comparison of the results of concomitant radiofrequency ablation and sclerotherapy for varicose veins versus treatment in two different sessions

Protocol summary

Summary

The aim of this study is to compare the results of concomitant radiofrequency ablation and sclerotherapy for varicose veins versus treatment in two different sessions . 80 patients with lower limb 3-12 mm varicose veins eligible for radiofrequency ablation (RFA) will be recruited for this study and will be randomized by Randlist software into 2 equal groups.The intervention group will be undergone the standard RFA procedure and sclerotherapy of the smaller venous branches at the same session. In the control group sclerotherapy will be deferred for two weeks after the RFA session. In both groups post-procedural ambulation is encouraged and compression stocking applied for 28 days.The following primary outcome measures will be collected by a questionnaire to compare between the two groups: pain, ecchymosis, erythema, hematoma, hyperpigmentation, paresthesias, phlebitis, skin infection, deep vein thrombosis, pulmonary embolism, arterial damage, nerve damage, skin burns. Follow-up of the patients will be continued till 2 month after the last procedure.

General information

Acronym

IRCT registration information

IRCT registration number: **IRCT2017030916473N8**
Registration date: **2017-03-14, 1395/12/24**
Registration timing: **registered_while_recruiting**

Last update:
Update count: **0**

Registration date

2017-03-14, 1395/12/24

Registrant information

Name

Farzad Kakaei

Name of organization / entity

Tabriz University of Medical Sciences

Country

Iran (Islamic Republic of)

Phone

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Recruitment status

Recruitment complete

Funding source

Tabriz University of Medical Sciences

Expected recruitment start date

2016-03-20, 1395/01/01

Expected recruitment end date

2017-03-20, 1395/12/30

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Comparison of the results of concomitant radiofrequency ablation and sclerotherapy for varicose veins versus treatment in two different sessions

Public title

Treatment of varicose veins

Purpose

Treatment

Inclusion/Exclusion criteria

Inclusion criteria: age between 18-75 years; visible varicose veins in lower limbs; saphenofemoral junction reflux confirmed by doppler sonography. Exclusion criteria: inability to tolerate the supine position; inability

to tolerate the procedure under local anaesthesia; uncontrolled local infection; concomitant ischemic symptoms in lower limbs; deep vein thrombosis; diabetes mellitus; use of any anticoagulants; any uncontrolled systemic disease such as terminal cancer patients or connective tissue diseases; lymphedema; pregnancy; history of thrombophilia; veins less than 3 mm or larger than 12 mm; tortuous vein

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: **80**

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
Tabriz University Of Medical Sciences

Street address
Golgasht St.

City
Tabriz

Postal code
5166614695

Approval date
2017-02-20, 1395/12/02

Ethics committee reference number
IR.TBZMED.REC.1395.1241

Health conditions studied

1

Description of health condition studied
Varicose veins

ICD-10 code
I83

ICD-10 code description
Varicose veins of lower extremities

Primary outcomes

1

Description
postoperative pain

Timepoint
days 1,3,7,14,28 after the operation

Method of measurement
with face pain scale

2

Description
operative site erythema

Timepoint
days 1,3,7,14,28 after the operation

Method of measurement
physical exam

3

Description
operative site echymosis

Timepoint
days 1,3,7,14,28 after the operation

Method of measurement
physical exam

4

Description
operative site hematoma

Timepoint
days 1,3,7,14,28 after the operation

Method of measurement
physical exam

5

Description
operative site infection

Timepoint
days 1,3,7,14,28 after the operation

Method of measurement
physical exam

6

Description
skin burn in the operative site

Timepoint
days 1,3,7,14,28 after the operation

Method of measurement
physical exam

7

Description
paresthesia in the operative site

Timepoint

days 1,3,7,14,28 after the operation
Method of measurement
physical exam

8

Description
arterial damage in operative site
Timepoint
days 1,3,7,14,28 after the operation
Method of measurement
physical exam

9

Description
hyperpigmentation at operative site
Timepoint
days 1,3,7,14,28 after the operation
Method of measurement
physical exam

10

Description
deep vein thrombosis
Timepoint
days 1,3,7,14,28 after the operation
Method of measurement
physical exam and doppler sonography if needed

11

Description
superficial vein phlebitis
Timepoint
days 1,3,7,14,28 after the operation
Method of measurement
physical exam

Secondary outcomes

1

Description
pulmonary embolism
Timepoint
days 1, 3, 7 and 28 after the operation
Method of measurement
physical exam and imaging studies if needed

2

Description
return to work
Timepoint
days after the operation
Method of measurement
questionnare

Intervention groups

1

Description
The intervention group will be undergone the standard RFA procedure and sclerotherapy of the smaller venous territories at the same session.
Category
Treatment - Surgery

2

Description
The control group will be undergone varicose vein radiofrequency ablation in one session and sclerotherapy will be deferred for another session two weeks later.
Category
Treatment - Surgery

Recruitment centers

1

Recruitment center
Name of recruitment center
Surgery unit of Tabriz Imam Reza hospital
Full name of responsible person
Farzad Kakaei
Street address
Surgery group, Imam Reza hospital
City
Tabriz

Sponsors / Funding sources

1

Sponsor
Name of organization / entity
Tabriz University Of Medical Sciences
Full name of responsible person
Mohammad Reza Rashidi
Street address
Golgasht St.,
City
Tabriz
Grant name
Grant code / Reference number
Is the source of funding the same sponsor organization/entity?
Yes
Title of funding source
Tabriz University Of Medical Sciences
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
Tabriz University Of Medical Sciences
Full name of responsible person
Farzad Kakaei
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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)
empty
Study Protocol
empty
Statistical Analysis Plan
empty
Informed Consent Form
empty
Clinical Study Report
empty
Analytic Code
empty
Data Dictionary
empty