

Clinical Trial Protocol

Iranian Registry of Clinical Trials

20 Jun 2026

Evaluation of addition of asymmetric compression dressing after thermal or chemical or surgical ablation of varicose veins to routine use of class II compression stockings (20mmHg pressure)

Protocol summary

Study aim

The aim of this study is to provide valuable insights into the effectiveness of asymmetrical dressing in addition to Class II compression stockings versus Class II stockings alone in reducing post-operative pain and enhancing recovery after varicose veins treatment.

Design

Two arm parallel group randomised trial with blinded postoperative care and outcome assessment

Settings and conduct

Patients with CEAP C2-C4 and significant reflux in GSV, AASV, PASV, SSV, who have visited the Vascular Surgery Clinic of the Shohada Tajrish hospital. 18-65 years old and no prior history of venous intervention on the affected limb. After EVTA, concomitant sclerotherapy and/or microphlebectomy. Participants in case group (asymmetrical dressing + Class 2 compression stocking) and control group Class 2 compression stocking. The pain score is assessed using the visual analog scale (VAS) on Day 3 and day 10 following the procedure. Pain scores, return time to normal activities, and ecchymosis and thrombophlebitis are assessed. Patients are followed up in terms of relapse and satisfaction within 6 months of treatment.

Participants/Inclusion and exclusion criteria

Patients 18-65 years old with CEAP (C2-C4) varicose veins and significant reflux detected in duplex ultrasound in the GSV, AASV, PASV, or SSV after EVTA and concomitant sclerotherapy and/or micro phlebectomy are entered into this randomized controlled trial.

Intervention groups

At the end of the operation participants in the intervention group will receive asymmetrical compression dressing using vibrill or foam under class II compression stockings for 72 hours and in the control group class II compression stockings alone administered for 72 hours

Main outcome variables

Pain score; Return time to normal activities; Ecchymosis; Thrombophlebitis; Recurrence; overall satisfaction

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20170614034531N1**
Registration date: **2023-09-24, 1402/07/02**
Registration timing: **registered_while_recruiting**

Last update: **2023-09-24, 1402/07/02**

Update count: **0**

Registration date

2023-09-24, 1402/07/02

Registrant information

Name

Niki Tadayon

Name of organization / entity

Country

Iran (Islamic Republic of)

Phone

+98 21 2272 1144

Email address

ntadayon@sbmu.ac.ir

Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2023-09-18, 1402/06/27

Expected recruitment end date

2023-11-18, 1402/08/27

Actual recruitment start date

empty
Actual recruitment end date
empty
Trial completion date
empty

Scientific title
Evaluation of addition of asymmetric compression dressing after thermal or chemical or surgical ablation of varicose veins to routine use of class II compression stockings (20mmHg pressure)

Public title
Evaluation of asymmetric compression dressing after thermal or chemical or surgical ablation of varicose veins.

Purpose
Treatment

Inclusion/Exclusion criteria
Inclusion criteria:
Patients with CEAP (C2-C4) varicose veins and significant reflux in duplex ultrasound in truncal veins (GSV, AASV,PASV, or SSV)

Exclusion criteria:
Any kind of previous treatment on the venous system of the affected limb. Prior history of DVT in the affected limb

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

Gender
Both

Phase
N/A

Groups that have been masked

- Participant
- Outcome assessor
- Data analyser

Sample size
Target sample size: **80**

Randomization (investigator's opinion)
Randomized

Randomization description
Random allocation Numbers 1- 80 are poured into the container, then 40 numbers are removed and registered without replacement, which will be the intervention group.

Blinding (investigator's opinion)
Double blinded

Blinding description
The patient is blind about the type of dressing under the compression stocking. (The foam additional compression is located under the well bonde and only the scrub nurse is aware of the dressing who does not play a role in the next stages of the study) The clinical evaluator (assistant) visits the patient after the removal of the dressing so will be blinded about the kind of dressing. Data analyzers are also blinded.

Placebo
Not used

Assignment
Parallel

Other design features

Secondary Ids
empty

Ethics committees

1

Ethics committee

Name of ethics committee

Research Ethics Committees of Laser Application
Research Center in Medical Sciences, Shahid Beheshti

Street address

Shardari

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Postal code

1989934148

Approval date

2023-09-13, 1402/06/22

Ethics committee reference number

IR.SBMU.LASER.REC.1402.022

Health conditions studied

1

Description of health condition studied

varicose vein

ICD-10 code

183.9

ICD-10 code description

Varicose veins of lower extremities without ulcer or inflammation

Primary outcomes

1

Description

Pain score with visual analogue scale (VAS)

Timepoint

3rd and 10th day post operative

Method of measurement

Visual Analogue Scale

Secondary outcomes

1

Description

Recurrence

Timepoint

6 months post operative

Method of measurement

Duplex sonography

Intervention groups

1

Description

Intervention group:

Category

Treatment - Other

2

Description

Control group:

Category

Treatment - Other

Recruitment centers

1

Recruitment center

Name of recruitment center

Shohada Tajrish hospital

Full name of responsible person

Niki Tadayon

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Shahrdari

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Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Shahid Beheshti University of Medical Sciences

Full name of responsible person

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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

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

Person responsible for general inquiries

Contact

Name of organization / entity

Shahid Beheshti University of Medical Sciences

Full name of responsible person

Niki Tadayon

Position

Assistant professor

Latest degree

Subspecialist

Other areas of specialty/work

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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

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

All data can be shared

When the data will become available and for how long

After publication

To whom data/document is available

Academic Investigators

Under which criteria data/document could be used

Analysis on data is approved

From where data/document is obtainable

E-Mail: ntadayonmd@gmail.com

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

In one month

Comments