

# Clinical Trial Protocol

## Iranian Registry of Clinical Trials

10 Jun 2026

### Effect of surgery versus radiofrequency ablation method on treatment varicose veins: a randomized clinical trial

#### Protocol summary

##### Study aim

To assess the effect of surgery versus radiofrequency ablation method on treatment varicose veins

##### Design

This is a Phase III randomized clinical trial with a control group, in which eligible patients will be randomly assigned to the intervention and control groups using drawing of lots.

##### Settings and conduct

This study will be conducted at the Besat Hospital in Hamadan city, involving 50 eligible patients with varicose veins of the lower limbs. The patients will be randomly assigned to the intervention groups through the drawing of lots. However, it should be noted that blinding is not feasible in this trial.

##### Participants/Inclusion and exclusion criteria

Inclusion criteria: Age 18 to 80 years Varicose veins of the lower limbs Saphenofemoral insufficiency Exclusion criteria: Insufficiency in the deep venous system

##### Intervention groups

Intervention group: The radiofrequency ablation catheter is pushed into the vein lumen and the entire length of the great saphenous vein is blocked with a temperature of 120 degrees Celsius for 20 seconds from the saphenofemoral junction to the catheter entry point.  
Intervention group 2: Removal of varicose veins of the great saphenous vein surgically under general anesthesia

##### Main outcome variables

Primary outcome: Saphenous vein recanalization rate; recurrence of saphenous femoral reflux Secondary outcome: Deep vein thrombosis; saphenous nerve damage

#### General information

##### Reason for update

##### Acronym

##### IRCT registration information

IRCT registration number: **IRCT20120215009014N487**

Registration date: **2023-10-29, 1402/08/07**

Registration timing: **prospective**

Last update: **2023-10-29, 1402/08/07**

Update count: **0**

##### Registration date

2023-10-29, 1402/08/07

##### Registrant information

###### Name

Jalal Poorolajal

###### Name of organization / entity

Department of Epidemiology & Biostatistics Hamadan University of Medical Sciences

###### Country

Iran (Islamic Republic of)

###### Phone

+98 81 1838 0090

###### Email address

poorolajal@umsha.ac.ir

##### Recruitment status

**Recruitment complete**

##### Funding source

##### Expected recruitment start date

2023-11-22, 1402/09/01

##### Expected recruitment end date

2024-01-20, 1402/10/30

##### Actual recruitment start date

empty

##### Actual recruitment end date

empty

##### Trial completion date

empty

##### Scientific title

Effect of surgery versus radiofrequency ablation method on treatment varicose veins: a randomized clinical trial

**Public title**

Effect of surgery versus radiofrequency ablation method on treatment varicose veins

**Purpose**

Treatment

**Inclusion/Exclusion criteria****Inclusion criteria:**

Age 18 to 80 years  
Varicose veins of the lower limbs  
Saphenofemoral insufficiency

**Exclusion criteria:**

Insufficiency in the deep venous system

**Age**

From **18 years** old to **80 years** old

**Gender**

Both

**Phase**

3

**Groups that have been masked**

*No information*

**Sample size**

Target sample size: **50**

**Randomization (investigator's opinion)**

Randomized

**Randomization description**

Random allocation of patients to intervention and control groups by lottery. For this purpose, we prepare two sheets, write "intervention" on one and "control" on the other. Then, with each patient's visit, one of the sheets is randomly taken and the patient is assigned to the intervention or control group.

**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 Hamadan University of Medical Sciences

**Street address**

Vice-chancellor for Research and Technology,  
Hamadan University of Medical Sciences, Fahmideh Ave

**City**

Hamadan

**Province**

Hamadan

**Postal code**

6517838695

**Approval date**

2023-07-01, 1402/04/10

**Ethics committee reference number**

IR.UMSHA.REC.1402.289

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

Varicose veins of the lower limbs

**ICD-10 code**

I83

**ICD-10 code description**

Varicose veins of lower extremities

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

Saphenous vein recanalization rate

**Timepoint**

One week, 3 months and 6 months after the intervention

**Method of measurement**

Using Doppler ultrasound

**2****Description**

Recurrence of saphenous femoral reflux

**Timepoint**

One week, 3 months and 6 months after the intervention

**Method of measurement**

Using Doppler ultrasound

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

Deep vein thrombosis

**Timepoint**

One week, 3 months and 6 months after intervention

**Method of measurement**

By clinical examination

**2****Description**

Saphenous nerve damage

**Timepoint**

One week, 3 months and 6 months after intervention

**Method of measurement**

By clinical examination

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

Intervention group 1: The radiofrequency ablation

catheter is pushed into the vein lumen and the entire length of the great saphenous vein is blocked with a temperature of 120 degrees Celsius for 20 seconds from the saphenofemoral junction to the catheter entry point.

**Category**

Treatment - Devices

**2****Description**

Intervention group 2:Removal of varicose veins of the great saphenous vein surgically under general anesthesia

**Category**

Treatment - Surgery

**Recruitment centers****1****Recruitment center****Name of recruitment center**

Besat Hospital in Hamadan city

**Full name of responsible person**

Fatemeh Kazemi Afshar

**Street address**

Besat Hospital, Shahed Square

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**Sponsors / Funding sources****1****Sponsor****Name of organization / entity**

Hamedan University of Medical Sciences

**Full name of responsible person**

Dr. Reza Shokoohi

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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**

Hamedan 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**

Hamedan University of Medical Sciences

**Full name of responsible person**

Fatemeh Kazemi Afshar

**Position**

Medical Student

**Latest degree**

Medical doctor

**Other areas of specialty/work**

General Practitioner

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**Person responsible for scientific inquiries****Contact****Name of organization / entity**

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Medical doctor

**Other areas of specialty/work**

General Surgery

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## Person responsible for updating data

### Contact

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## Sharing plan

### Deidentified Individual Participant Data Set (IPD)

Undecided - It is not yet known if there will be a plan to make this available

### Study Protocol

Undecided - It is not yet known if there will be a plan to make this available

### Statistical Analysis Plan

Undecided - It is not yet known if there will be a plan to make this available

### Informed Consent Form

Undecided - It is not yet known if there will be a plan to make this available

### Clinical Study Report

Undecided - It is not yet known if there will be a plan to make this available

### Analytic Code

Undecided - It is not yet known if there will be a plan to make this available

### Data Dictionary

Undecided - It is not yet known if there will be a plan to make this available