

# Clinical Trial Protocol

## Iranian Registry of Clinical Trials

10 Jun 2026

### Studying the effect of inspiratory breathing exercises on the quality of life and vascular flow of patients with lower limb venous insufficiency referred to Hospital

#### Protocol summary

##### Study aim

Studying the effect of inspiratory breathing exercises on the quality of life and vascular flow of patients with lower limb venous insufficiency referred to the Hospital

##### Design

The present clinical trial study has 1 control group and 1 intervention group, with parallel and double-blind groups, randomized, and a sample size of 50 patients.

##### Settings and conduct

This study is a clinical trial in patients with lower extremity venous insufficiency referred to Taleghani Hospital. After signing the consent form, a quality of life questionnaire and lower extremity plethysmography will be completed by a vascular surgeon and saphenous vein refill time (VRT) will be measured. In the control group, calf muscle strengthening exercises will be performed, and in the intervention group, patients will use the IMT device in addition to calf muscle strengthening exercises. The patient and the surgeon are blinded.

##### Participants/Inclusion and exclusion criteria

The inclusion criteria included the age range of 18 to 65 years, having informed consent to participate in the study, having no previous history of performing breathing exercises or other similar protocols, a definitive diagnosis of lower extremity venous insufficiency, and the exclusion criteria included the patient's unwillingness to continue participating in the study, worsening of the patient's condition or death before the end of the 2-month study period, and starting new treatment protocols for the patient that interfered with inspiratory breathing exercises.

##### Intervention groups

In the control group, calf muscle strengthening exercises will be performed three sessions per week. In the intervention group, in addition to calf muscle strengthening exercises, inspiratory breathing exercises will be performed using the inspiratory muscle training

(IMT) device.

##### Main outcome variables

Quality of lie, Venous refilling time

#### General information

##### Reason for update

##### Acronym

##### IRCT registration information

IRCT registration number: **IRCT20251122068071N1**

Registration date: **2025-11-25, 1404/09/04**

Registration timing: **prospective**

Last update: **2025-11-25, 1404/09/04**

Update count: **0**

##### Registration date

2025-11-25, 1404/09/04

##### Registrant information

##### Name

Roya Ghazvineh

##### Name of organization / entity

##### Country

Iran (Islamic Republic of)

##### Phone

+98 21 2303 1111

##### Email address

dr.ghazvineh@gmail.com

##### Recruitment status

**recruiting**

##### Funding source

##### Expected recruitment start date

2025-12-22, 1404/10/01

##### Expected recruitment end date

2026-07-23, 1405/05/01

##### Actual recruitment start date

empty

**Actual recruitment end date**

empty

**Trial completion date**

empty

**Scientific title**

Studying the effect of inspiratory breathing exercises on the quality of life and vascular flow of patients with lower limb venous insufficiency referred to Hospital

**Public title**

Studying the effect of inspiratory breathing exercises in patients with lower limb venous insufficiency

**Purpose**

Treatment

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

Age range 18 to 65 years Having informed consent to participate in the study No previous experience with breathing exercises or other similar protocols Definitive diagnosis of lower extremity venous insufficiency

**Exclusion criteria:**

Patient's unwillingness to continue participating in the study Deterioration of the patient's condition or death before the end of the 2-month study period Initiating new treatment protocols for the patient that interfere with inspiratory breathing exercises.

**Age**

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

**Gender**

Both

**Phase**

3

**Groups that have been masked**

- Participant
- Outcome assessor

**Sample size**

Target sample size: **50**

**Randomization (investigator's opinion)**

Randomized

**Randomization description**

Simple randomization method, individual randomization unit, randomization tool: random number table, double blind. For randomization, the Simple Randomization method is used using a random number table. For this purpose, two groups (A, B) are considered. We choose one of the rows of the random number table at will and we know that the numbers in each row will be between 0 and 9. Then we assign the numbers 0-4 to treatment A and the numbers 5-9 to treatment B. Suppose the numbers for the first row are as follows: 0, 5, 2, 7, 8, 4. Therefore, the number 0 is assigned to treatment A, the number 5 to treatment B, the number 2 to treatment A, .... Therefore, the first person receives treatment A, the second person receives treatment B ....

**Blinding (investigator's opinion)**

Double blinded

**Blinding description**

Patients are not aware that the IMT device is the main component of the intervention. Both groups have exercises, so no obvious sense of difference is created.

Also, the vascular surgeon is blinded to the group allocation.

**Placebo**

Not used

**Assignment**

Parallel

**Other design features****Secondary Ids**

empty

**Ethics committees****1****Ethics committee****Name of ethics committee**

Ethics committee of Shahid Beheshti University of Medical Sciences

**Street address**

Yemen St., Shahid Chamran Highway

**City**

Tehran

**Province**

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**Postal code**

1956944413

**Approval date**

2025-11-05, 1404/08/14

**Ethics committee reference number**

IR.SBMU.MSP.REC.1404.519

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

Lower Limb Venous Insufficiency

**ICD-10 code**

I87.2

**ICD-10 code description**

Venous insufficiency (chronic) (peripheral)

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

Quality of life

**Timepoint**

Before the intervention and after the end of eight weeks of intervention

**Method of measurement**

Quality of life questionnaire for patients with venous insufficiency

**2****Description**

Venous refilling time

**Timepoint**

Quality of life questionnaire for patients with venous insufficiency

**Method of measurement**

Plethysmography

**Secondary outcomes**

empty

**Intervention groups**

**1**

**Description**

Control group: In the control group, calf muscle strengthening exercises will be performed three sessions per week as routine care, with calf strengthening exercises performed two sessions per week in three sets and 10 repetitions; for the first month, three gastrosoleus stretches, two-legged cuff raises while sitting on a chair, and two-legged cuff raises on a flat surface will be performed; in the second month of intervention, three exercises: single-legged cuff raises on a flat surface, two-legged cuff raises on a board, and tiptoe walking for three to one minute will be added to the previous exercises.

**Category**

Rehabilitation

**2**

**Description**

Intervention group: In the intervention group, in addition to calf muscle strengthening exercises, patients will be given inspiratory breathing exercises using the IMT device for 8 weeks, five days per week, twice a day, and 30 breaths per session, with a gradual increase in the degree of difficulty (one degree per week).

**Category**

Rehabilitation

**Recruitment centers**

**1**

**Recruitment center**

**Name of recruitment center**

Shahid Taleghani Hospital

**Full name of responsible person**

Roya Ghazvineh

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Yemen St., Shahid Chamran highway

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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**

Roya Ghazvineh

**Position**

Resident

**Latest degree**

Specialist

**Other areas of specialty/work**

Sport Medicine

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## Person responsible for scientific inquiries

**Contact**

**Name of organization / entity**

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Associate Professor

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## Person responsible for updating data

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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