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)

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+98 21 2303 1111

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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
Tehran
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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Sponsors / Funding sources

1

Sponsor

Name of organization / entity

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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

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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