# Clinical Trial Protocol
# Iranian Registry of Clinical Trials

07 Nov 2026

## Investigating the effect of manual lymph drainage and exercise in patients with lymphedema

### Protocol summary

**Study aim**
Investigating the effect of manual lymph drainage of exercise in patients with lymphedema

**Design**
Clinical trial with control group, with parallel groups, non-randomized, on 130 patients. A non-random method was used to divide the groups into control and intervention groups.

**Settings and conduct**
First, patients with lymphedema are referred to Mubasher Hamedan Clinic by oncology and radiotherapy specialists, and they are included in the study if they meet the eligibility criteria. People are placed in two groups of manual lymphatic drainage and exercise randomly; first, in each group, the variables of limb volume, pain, quality of life, and range of motion of the shoulder are evaluated and investigated, then in the manual lymphatic drainage group, the lymphatic pathways involved and certain are drained by massage and these pathways and lymph nodes are used to change the path of lymph fluid rich in protein from the organ or the swollen part of the body to the venous system, and in the exercise group, a series of exercises It is given to the patient according to the research done and at the end the variables are re-evaluated.

**Participants/Inclusion and exclusion criteria**
inclusion criteria: people with lymphedema, women aged 25-68 Non-entry conditions: existence of disease problems, existence of aortic aneurysm

**Intervention groups**
The intervention group includes patients with lymphedema who receive manual lymphatic drainage. The comparison group includes patients with lymphedema who receive the exercise therapy protocol.

**Main outcome variables**
Including evaluation of the organ environment through tape measure, evaluation of pain score using numerical rating scale, and evaluation of functional disability level through questionnaire.

### General information

**Reason for update**

**Acronym**

**IRCT registration information**
IRCT registration number: **IRCT20160704028776N2**
Registration date: **2025-01-14, 1403/10/25**
Registration timing: **prospective**

Last update: **2025-01-14, 1403/10/25**
Update count: **0**

**Registration date**
2025-01-14, 1403/10/25

**Registrant information**
**Name**
**Name of organization / entity**
**Country**
Iran (Islamic Republic of)
**Phone**
+98 77548496
**Email address**
roosta@sbmu.ac.ir

**Recruitment status**
**Recruitment complete**

**Funding source**

**Expected recruitment start date**
2025-01-19, 1403/10/30

**Expected recruitment end date**
2025-08-16, 1404/05/25

**Actual recruitment start date**
empty

**Actual recruitment end date**
empty

**Trial completion date**
empty

**Scientific title**
Investigating the effect of manual lymph drainage and

exercise in patients with lymphedema

**Public title**
The effect of manual lymph drainage and exercise
**Purpose**
Supportive
**Inclusion/Exclusion criteria**
**Inclusion criteria:**
People with lymphedema who have been referred to the physiotherapy clinic by radiotherapy and oncology specialists Women aged 25 to 65 years No heart problems Absence of aortic aneurysm Absence of any musculoskeletal-neurological disorder that is not related to the complications of cancer Absence of autoimmune diseases such as rheumatoid arthritis
**Exclusion criteria:**
The patient's lack of consent to cooperate at any stage of the research
**Age**
From **25 years** old to **68 years** old
**Gender**
Female

**Phase**
N/A
**Groups that have been masked**
*No information*
**Sample size**
Target sample size: **130**
**Randomization (investigator's opinion)**
Not 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**
Ethics Committee of Shahid Beheshti University of Medical Sciences
**Street address**
Shahid Beheshti University of Medical Sciences, Shahid Beheshti University of Medical Sciences, Faculty of Rehabilitation Sciences, in front of Bo Ali Hospital, Imam Hossein Square, Damavand Street (New Tehran), Tehran
**City**
Tehran
**Province**
Tehran
**Postal code**
1616913111
**Approval date**
2024-05-06, 1403/02/17
**Ethics committee reference number**
IR.SBMU.RETECH.REC.1403.055

## Health conditions studied

### 1

**Description of health condition studied**
Lymphedema
**ICD-10 code**
I97.2
**ICD-10 code description**
Postmastectomy lymphedema syndrome

## Primary outcomes

### 1

**Description**
Organ volume: measuring the circumference of the limb with lymphedema
**Timepoint**
Before and after the intervention during the same session
**Method of measurement**
A standard tape measure tool was used to measure manual lymphatic drainage.

## Secondary outcomes

### 1

**Description**
Pain: score from 1 to 10 based on VAS scale
**Timepoint**
Before and after the intervention during the same session
**Method of measurement**
The measurement was done with a tape measure.

### 2

**Description**
Quality of life: checking people's quality of life using the score of the quality of life questionnaire
**Timepoint**
Before and after the intervention during the same session
**Method of measurement**
By evaluating the score of the quality of life questionnaire of the World Health Organization

### 3

**Description**
Shoulder range of motion: the degree of shoulder elevation angle
**Timepoint**

Before and after the intervention during the same session

**Method of measurement**

The movement angle of the shoulder is measured using a goniometer

## Intervention groups

### 1

**Description**

Manual lymph drainage group: In this study, one session of manual lymph drainage lasts for 2-3 hours, the most important part of manual lymph drainage is to identify the areas that need to be drained and also to identify healthy and necessary lymphatic pathways. These pathways and lymph nodes are used to change the path of protein-rich lymph fluid from the organ or the swollen part of the body to the venous system. The basis of the technique of manual lymph drainage is the basic strokes, which are: Rotary, pump, stationary circle, scoop. The common feature of all four techniques is having two phases, including the working or pressing phase and the rest or relaxing phase. All of these techniques are applied from the center to the periphery, in such a way that first the proximal areas are drained in order to prepare for the liquid collected in the distal parts. In the working phase of each stroke, the stimuli A stretch is applied to the subcutaneous tissue. The pressure in this phase should be so much that it causes the subcutaneous tissue to stretch on the underlying fascia to the extent of its elastic capacity. Applying gentle and directional pressure during the work phase causes the movement of lymph fluid in the right direction and causes the lymph to drain in the desired direction. The best result is achieved when each work phase lasts one second and 5 to 7 times at each point in a fixed pattern. Or a varied pattern is repeated.

**Category**

Rehabilitation

### 2

**Description**

Intervention group: exercise: In this study, patients exercise for one session and for a duration of 30 minutes according to the therapeutic exercise protocol. The patients' exercise protocol includes diaphragmatic breathing, stretching exercises of the upper limbs, including stretching of the flexor and extensor muscles of the arm and wrist; The patient keeps each stretching exercise for 15-30 seconds and repeats two sets of three. While performing diaphragmatic breathing, the patient's position is such that the patient's fingers are placed in front of the sternum and the patient starts performing diaphragmatic breathing. When performing exercises, compression bandages or compression bandages should be used. Tight and restrictive clothes should not be used during exercise. Movements should be slow and controlled.

**Category**

Rehabilitation

## Recruitment centers

### 1

**Recruitment center**

**Name of recruitment center**

Shahid Beheshti University of Medical Sciences, Shahid Beheshti University of Medical Sciences, Facu

**Full name of responsible person**

Dr. Mohammad Mohsen Roostae

**Street address**

Shahid Beheshti University of Medical Sciences, Shahid Beheshti University of Medical Sciences, Faculty of Rehabilitation Sciences, in front of Bo Ali Hospital, Imam Hossein Square, Damavand Street (New Tehran), Tehran

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1616913111

**Phone**

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**Email**

roosta@sbmu.ac.ir

## Sponsors / Funding sources

### 1

**Sponsor**

**Name of organization / entity**

Shahid Beheshti University of Medical Sciences

**Full name of responsible person**

Dr. Mohammad Mohsen Roostayi

**Street address**

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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

**Province**

Tehran

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## Person responsible for general inquiries

**Contact**

**Name of organization / entity**

Shahid Beheshti University of Medical Sciences

**Full name of responsible person**

Dr. Mohammad Mohsen Roostae

**Position**

Associate Professor

**Latest degree**

Ph.D.

**Other areas of specialty/work**

Physiotherapy

**Street address**

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## Person responsible for updating data

**Contact**

**Name of organization / entity**

Shahid Beheshti University of Medical Sciences

**Full name of responsible person**

Dr. Mohammad Mohsen Roostae

**Position**

Associate Professor

**Latest degree**

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**Other areas of specialty/work**

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## Person responsible for scientific inquiries

**Contact**

**Name of organization / entity**

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**Full name of responsible person**

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**Position**

Associate Professor

**Latest degree**

Ph.D.

**Other areas of specialty/work**

Physiotherapy

**Street address**

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**City**

Tehran

## 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**

No - There is not 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