Clinical Trial Protocol
Iranian Registry of Clinical Trials

07 Nov 2026

Comparison of the additional effect of myofascial release or intermittent pneumatic compression on combined decongestive therapy in improving Sonography and Sonoelastographic parameters and clinical symptoms in women with breast cancer related lymphoedema

Protocol summary

Study aim

Assessment of the additive therapeutic effects of myofascial release over combined decongestion therapy(CDT) compared to intermittent pneumatic compression over CDT on changes in upper limb volume and diameter, physical tissue characteristics, changes in tissue thickness, pain parameters, range of motion and quality of life in women with lymphedema.

Design

A controlled, single-blind, randomized, block-based clinical trial with 45 patients

Settings and conduct

Patients with lymphedema are referred to a physiotherapist by a surgeon or oncologist and an initial assessment will be performed to determine eligibility. Patients will then randomly assigned to one of three treatment groups and will assess by a blinded sonographer and physiotherapist at the Imam Khomeini Medical Complex. Patients will receive the treatments for ten sessions and the assessments will be repeated at the end of the tenth session.

Participants/Inclusion and exclusion criteria

Women aged 25-65 years, undergone a total/partial mastectomy or lumpectomy, stage 2 unilateral lymphedema, had received at least one of the chemotherapy or radiotherapy treatment, who were excluded from the study if they had cancer recurrence, infection, or a history of lymphedema treatment within the past 6 months

Intervention groups

Group 1 (Control): CDT including manual lymph drainage , multilayer compression bandage, skin and nail care education, and lymphatic drainage exercises. Group 2: Myofascial release with CDT Group 3: intermittent pneumatic compression with CDT

Main outcome variables

Limb volume (water displacement method), limb diameter (tape), pain intensity (numerical pain rating scale), pressure pain threshold (algometer), shoulder range of motion (goniometer), quality of life questionnaire, skin and subcutaneous tissue thickness (ultrasound), shear wave velocity, tissue stiffness, and Elastogram image (shear wave Elastosonography)

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20250304064934N1**
Registration date: **2025-04-13, 1404/01/24**
Registration timing: **prospective**

Last update: **2025-04-13, 1404/01/24**
Update count: **0**

Registration date

2025-04-13, 1404/01/24

Registrant information

Name

sahar zamani

Name of organization / entity

Country

Iran (Islamic Republic of)

Phone

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Recruitment status

Recruitment complete

Funding source

Expected recruitment start date
2025-04-20, 1404/01/31
Expected recruitment end date
2025-09-20, 1404/06/29
Actual recruitment start date
empty
Actual recruitment end date
empty
Trial completion date
empty

Scientific title
Comparison of the additional effect of myofascial release or intermittent pneumatic compression on combined decongestive therapy in improving Sonography and Sonoelastographic parameters and clinical symptoms in women with breast cancer related lymphoedema

Public title
Comparison of myofascial release and intermittent pneumatic compression in breast cancer related lymphedema
Purpose
Treatment
Inclusion/Exclusion criteria
Inclusion criteria:
Performing a total/partial mastectomy, or lumpectomy (with or without axillary lymph node dissection) and diagnosing unilateral lymphedema stage 2 (based on the World Society of Lymphology classification) following breast cancer by a physician Confirmed lymphedema according to the following criteria (at least one of the following conditions must be present): At least 2 cm difference in the circumference of the two upper limbs At least 10% difference in the volume of the two upper limbs At least 200 ml difference in the volume of the two upper limbs Completion of chemotherapy or radiotherapy treatment sessions at least 6 weeks prior to study entry Receiving at least one of the treatments chemotherapy or radiotherapy in addition to breast surgery BMI<35
Exclusion criteria:
Breast cancer recurrence or metastasis to other areas Infection History of lymphedema treatment in the past 6 months Untreated cardiovascular and kidney diseases Deep vein thrombosis or other vascular pathologies in the upper extremities Uncontrolled hypertension Communication disorders and mental problems Neuromuscular disease that causes sensory disturbances, decreased deep tendon reflexes, and changes in motor strength History of cellulitis in the last 6 weeks (redness, swelling, and sudden pain in a lymphatic organ) Severe joint pain or deformity due to arthritis or any other musculoskeletal problem History of shoulder or upper extremity surgery or deep scarring from wounds or burns in the upper extremity and upper trunk
Age
From **25 years** old to **65 years** old
Gender
Female

Phase
N/A

Groups that have been masked

- Outcome assessor

Sample size
Target sample size: **45**
Randomization (investigator's opinion)
Randomized
Randomization description
The block randomization method with a block size of 6 will be divided equally (ratio 1:1:1) into three groups
Blinding (investigator's opinion)
Single blinded
Blinding description
Patient assessment will be performed by a blinded radiologist and physiotherapist who are unaware of the type of intervention the patients are receiving
Placebo
Not used
Assignment
Parallel
Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee
Name of ethics committee
Ethics committee of Tehran University of Medical Sciences
Street address
Tehran University of Medical Sciences, Ghods St., Keshavarz Blvd.
City
Tehran
Province
Tehran
Postal code
1148965111
Approval date
2025-02-17, 1403/11/29
Ethics committee reference number
IR.TUMS.IKHC.REC.1403.522

Health conditions studied

1

Description of health condition studied
Lymphoedema
ICD-10 code
I97.2
ICD-10 code description
Postmastectomy lymphoedema syndrome

Primary outcomes

1

Description
Changes in the thickness of cutaneous and subcutaneous tissue on the affected and non affected sides of patients with lymphedema
Timepoint
Before the interventions start and after the treatment sessions are completed
Method of measurement
Sonography

2

Description
Shear wave velocity and tissue stiffness of the subcutaneous tissue
Timepoint
Before the interventions start and after the treatment sessions are completed
Method of measurement
Sonoelastography

Secondary outcomes

1

Description
Tissue stiffness distribution in Elastogram
Timepoint
Before the start of interventions and after the completion of treatment sessions
Method of measurement
Image J software

2

Description
Volume of affected and non affected upper limb
Timepoint
Before the start of interventions and after the completion of treatment sessions
Method of measurement
Water displacement volumetry

3

Description
Circumference of affected and non affected upper limb
Timepoint
Before the start of interventions and after the completion of treatment sessions
Method of measurement
Tape

4

Description
Pressure pain threshold
Timepoint
Before the start of interventions and after the completion of treatment sessions
Method of measurement
Pressure algometer

5

Description
Pain intansity
Timepoint
Before the start of interventions and after the completion of treatment sessions
Method of measurement
Numeric Pain Rating Scale

6

Description
Shoulder range of motion
Timepoint
Before the start of interventions and after the completion of treatment sessions
Method of measurement
Goniometer

7

Description
Quality of life
Timepoint
Before the start of interventions and after the completion of treatment sessions
Method of measurement
LLIS1 questionnaire

Intervention groups

1

Description
Control group: Combined decongestive therapy. Includes manual lymph drainage technique (for 30 minutes) by Foldi method , multi-layered compression bandage, skin and nail care education, and specific lymphatic drainage exercises. Patients in this group will receive 10 sessions, 5 times a week, for two weeks.
Category
Treatment - Other

2

Description
Intervention group: Myofascial release plus combined decongestive therapy. In addition to combined decongestion therapy, patients will receive fascial release techniques using gross stretch techniques for superficial tissues and focused stretch for more restricted tissues. This treatment will be performed on the anterior and posterior chest, pectoralis major and minor, latissimus dorsi, upper and middle trapezius, infraspinatus, supraspinatus, levator scapulae and deltoid, and scar fascia at the surgical site for a total of 30 minutes. The technique will be continued in each area until the release of restricted fascia is felt under the examiner's hand. The number of treatment sessions will be 10, the duration will be two weeks, and 5 times a

week.

Category

Treatment - Other

3

Description

Intervention group: Intermittent pneumatic compression plus combined decongestive therapy. In this group, in addition to the combined decongestion Therapy performed in the control group, the LX9 intermittent pneumatic compression device (4-chamber type) manufactured by Daesung Maref, South Korea, will also be used. the upper limb with lymphedema will be placed inside a flexible multi-chamber sleeve for 30 minutes at a pressure of 40-60 mm Hg with a inflation time of 60 seconds and a deflation time of 25 seconds. Patients will receive 10 sessions, 5 times per week, for two weeks.

Category

Treatment - Other

Recruitment centers

1

Recruitment center

Name of recruitment center

Imam Khomeini Hospital Complex

Full name of responsible person

Niloofar Ayoobi Yazdi

Street address

Imam Khomeini Hospital, Dr. Gharib Street, Keshavarz Boulevard,

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Sponsors / Funding sources

1

Sponsor

Name of organization / entity

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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

Tehran 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

Tehran University of Medical Sciences

Full name of responsible person

Sahar Zamani

Position

PHD student

Latest degree

Master

Other areas of specialty/work

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Sharing plan

Deidentified Individual Participant Data Set (IPD)
Yes - There is 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
Not applicable
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
Not applicable
Data Dictionary
Not applicable
Title and more details about the data/document
Information of outcomes before and after the intervention can be shared. All results from primary and secondary assessments will be presented as averages in Excel.
When the data will become available and for how long
Access starts 6 months after publishing of the results
To whom data/document is available
Access is possible for researchers working in academic and scientific institutions
Under which criteria data/document could be used
They can use the results for systematic review. Access is possible if academic and scientific responsibility is established.
From where data/document is obtainable
Applicants can send their application to the researcher's email address. sahar_zamanipt87@yahoo.com
What processes are involved for a request to access data/document
The applicant can access the information by providing valid proof of academic affiliation to the university by sending this proof to the researcher's email
Comments