

Clinical Trial Protocol

Iranian Registry of Clinical Trials

16 Sep 2026

Comparing the Effect of Combined Decongestive Therapy with or without Resistive Exercises on Edema Volume, Upper Limb Function, and Quality of Life among Women with Breast Cancer Related Lymphedema

Protocol summary

Study aim

Comparing the Effect of Combined Decongestive Therapy with or without Resistive Exercises on Edema Volume, Upper Limb Function, and Quality of Life among Women with Breast Cancer Related Lymphedema

Design

Randomized controlled trial with control group, double blinded Blocks of 4 will be used for randomization.

Settings and conduct

38 lymphedema patients in 2 groups will participate in this study. Both groups will be treated for 10 sessions. The assessor and the patient will be blinded.

Participants/Inclusion and exclusion criteria

Inclusion criteria: Women with breast cancer who had undergone treatments Cancer treatments finished at least 6 weeks ago Native Iranians or people who can read and write persian Patients with lymphedema diagnosis with one of these conditions: 1- At least 2 centimeters difference in upper limbs' circumference 2- At least 200 milliliters difference in upper limbs' volume 3- At least 5 percent difference in upper limbs' volume
Non inclusion criteria: Cancer recurrence Uncontrolled infection Untreated heart or kidney failure Deep vein thrombosis in upper limb Inability to participate in physiotherapy Inability to understand commands Uncontrolled hypertension Inflammatory neuromuscular disease Coronary artery disease Congestive heart failure Experiencing joint or muscle pain while doing active movements without resistance

Intervention groups

Control group: 10 sessions of combined decongestive therapy that consists of skin and nail care, manual lymph drainage, compression bandage and decongestive exercises. Intervention group: 10 sessions of combined decongestive therapy and 6 sessions of concurrent resistive exercise

Main outcome variables

Limb volume; limb circumference; dexterity; upper limb function; quality of life

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20230816059172N1**

Registration date: **2023-09-13, 1402/06/22**

Registration timing: **prospective**

Last update: **2023-09-13, 1402/06/22**

Update count: **0**

Registration date

2023-09-13, 1402/06/22

Registrant information

Name

Aisan Seyedi

Name of organization / entity

Country

Iran (Islamic Republic of)

Phone

+98 21 7753 3939

Email address

seyyedia1@gmail.com

Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2023-09-23, 1402/07/01

Expected recruitment end date

2024-05-21, 1403/03/01

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date
empty

Scientific title
Comparing the Effect of Combined Decongestive Therapy with or without Resistive Exercises on Edema Volume, Upper Limb Function, and Quality of Life among Women with Breast Cancer Related Lymphedema

Public title
Resistive exercise in lymphedema

Purpose
Treatment

Inclusion/Exclusion criteria
Inclusion criteria:
Women with breast cancer who had undergone needed treatments Patients who had finished their chemotherapy or radiotherapy at least 6 weeks ago Native Iranians or people who can read and write persian Patients with lymphedema diagnosis with one of these conditions: 1- At least 2 centimeters difference in upper limbs' circumference; 2-At least 200 milliliters difference in upper limbs' volume; 3- At least 5 percent difference in upper limbs' volume
Exclusion criteria:
Cancer recurrence Untreated heart or kidney failure People experiencing joint or muscle pain while doing active movements without resistance Uncontrolled infection Deep vein thrombosis in upper limb Inflammatory neuromuscular disease Coronary artery disease Congestive heart failure People who are unable to understand commands People who are unable to participate in physiotherapy Uncontrolled hypertension

Age
No age limit

Gender
Female

Phase
N/A

Groups that have been masked

- Participant
- Outcome assessor

Sample size
Target sample size: **38**

Randomization (investigator's opinion)
Randomized

Randomization description
Participants will be randomized by block balance randomization. They will be sorted by blocks of 4 into two groups. Sequence of blocks will be made by Randomization website.

Blinding (investigator's opinion)
Double blinded

Blinding description
The patients will be unaware of their group allocation. The assessor will be unaware of which group the participant has been allocated.

Placebo
Not used

Assignment

Factorial

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
School of rehabilitation, Pich-e-Shemiran, Enghelab St, District 12, Tehran
City
Tehran
Province
Tehran
Postal code
65111-11489
Approval date
2023-08-16, 1402/05/25
Ethics committee reference number
IR.TUMS.FNM.REC.1402.117

Health conditions studied

1

Description of health condition studied
Breast cancer related lymphedema
ICD-10 code
I97.2
ICD-10 code description
Postmastectomy lymphedema syndrome

Primary outcomes

1

Description
Quality of life
Timepoint
Before starting the intervention and at the end of treatment period
Method of measurement
Lymphedema life impact scale questionnaire

2

Description
Upper limb function
Timepoint
Before starting the intervention and at the end of treatment period
Method of measurement
Performing Upper limb functional test and dexterity test

Secondary outcomes

1

Description

Upper limb circumference

Timepoint

Before starting the intervention and at the end of treatment period

Method of measurement

Measuring tape

2

Description

Upper limb volume

Timepoint

Before starting the intervention and at the end of treatment period

Method of measurement

Measuring tape and calculator

Intervention groups

1

Description

Intervention group: Combined decongestional therapy which consists of compression bandage, skin and nail care, manual lymph drainage and exercise therapy will be performed for 10 sessions and 5 days per week. The participants will also perform 6 sessions of resistive exercise concurrently.

Category

Treatment - Other

2

Description

Control group: Combined decongestional therapy which consists of compression bandage, skin and nail care, manual lymph drainage and exercise therapy will be performed for 10 sessions and 5 days per week.

Category

Treatment - Other

Recruitment centers

1

Recruitment center

Name of recruitment center

Tehran University of Medical Sciences - School of Rehabilitation

Full name of responsible person

Aisan Seyedi

Street address

Tehran, District 12, Enghelab St. Pich-e-Shemiran

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Email

seyyedial@gmail.com

Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Tehran University of Medical Sciences

Full name of responsible person

Akbar Fotouhi

Street address

Tehran Province, Tehran, Keshavarz Blvd, P95V+4X7, Iran

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+98 21 8899 2970

Email

vcr@sina.tums.ac.ir

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

Aisan Seyedi

Position

Student

Latest degree

Bachelor

Other areas of specialty/work

Physiotherapy

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Person responsible for scientific inquiries

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Position

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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

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

Only the information about outcome measures will be shared.

When the data will become available and for how long

8 months after publication of the results

To whom data/document is available

Researchers who are affiliated to medical universities

Under which criteria data/document could be used

Data could only be processed after seeking permission from researchers.

From where data/document is obtainable

1- Email: seyedia1@gmail.com 2- Phone number
09128956585

What processes are involved for a request to access data/document

After sending the request and correspondence, data will be sent within 10 work days.

Comments