Clinical Trial Protocol
Iranian Registry of Clinical Trials

07 Nov 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 assesor 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 resistence

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 resistence 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 participanthas 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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65111-11489
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Email
seyyedia1@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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Tehran
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Postal code
65111-11489
Phone
+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
Street address

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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 researcers.

From where data/document is obtainable
1- Email: seyyedia1@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