Clinical Trial Protocol
Iranian Registry of Clinical Trials

07 Nov 2026

Comparing the Effect of Complex Decongestive physical Therapy and Combination of Intermittent Pneumatic Compression Pump and Complex Decongestive physical Therapy on Lymphedema Volume and Quality of Life in Patients with Breast Cancer

Protocol summary

Summary

The aim of this study is to compare the effect of Complex Decongestive physical Therapy and Combination of Intermittent Pneumatic Compression Pump and Complex Decongestive physical Therapy on Lymphedema Volume and Quality of Life in Patients with Breast Cancer. Inclusion criteria: Unilateral upper extremity lymphedema ; The severity of lymphedema with grade 2; No previous treatment for lymphedema Exclusion criteria: The return of cancer; infection in the arm; intolerance bandage. A total of 20 patients with breast cancer who underwent mastectomy and involved upper extremity lymphedema on affected side according to inclusion and exclusion criteria will be introduced by a specialist surgeon. Patients are randomly divided into two groups, first group are treated with Complex Decongestive physical Therapy and second group with combination of Intermittent Pneumatic compression Pump and Complex Decongestive physical Therapy for 2 weeks and 5 days a week . Treatments for complex Decongestive physical Therapy group include manual lymphatic drainage, multi-layer bandaging, exercise and skin and nail care. Treatments for combination of Intermittent Pneumatic Compression Pump and complex Decongestive physical Therapy group include manual lymphatic drainage, multi-layer bandaging, exercise, skin and nail care and Intermittent Pneumatic Compression device. The following outcome measures are evaluated before and after interventions: upper limb circumference by a tape, limb lymphedema volume using a volumeter and Quality of life by using of two particular questionnaires related to breast cancer.

General information

Acronym

IRCT registration information

IRCT registration number: **IRCT2016022726779N1**
Registration date: **2016-05-21, 1395/03/01**
Registration timing: **registered_while_recruiting**

Last update:
Update count: **0**

Registration date

2016-05-21, 1395/03/01

Registrant information

Name

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Name of organization / entity

Tehran Universaity of Medical Sciences, Faculty of Rehabilitation

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Recruitment status

Recruitment complete

Funding source

Deputy of research and technology of Tehran University of Medical Sciences

Expected recruitment start date

2016-05-04, 1395/02/15

Expected recruitment end date

2016-07-20, 1395/04/30

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title
Comparing the Effect of Complex Decongestive physical Therapy and Combination of Intermittent Pneumatic Compression Pump and Complex Decongestive physical Therapy on Lymphedema Volume and Quality of Life in Patients with Breast Cancer

Public title
The Effect of physical Therapy treatments in Patients with Breast Cancer
Purpose
Treatment
Inclusion/Exclusion criteria
Inclusion criteria: unilateral upper extremity lymphedema ; The severity of lymphedema with grade 2; No previous treatment for lymphedema Exclusion criteria: The return of cancer; infection in the arm; intolerance bandage.
Age
No age limit
Gender
Female

Phase
N/A
Groups that have been masked
No information
Sample size
Target sample size: **20**
Randomization (investigator's opinion)
Randomized
Randomization description
Blinding (investigator's opinion)
Single blinded
Blinding description
Placebo
Not used
Assignment
Parallel
Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee
Name of ethics committee
Deputy of Research and technology of Tehran University of Medical Sciences
Street address
Tehran- Bolvar Keshavarz Avenue- Entrance of Ghods Ave- Central organisation of University-Sixth Floor
City
Tehran
Postal code
Approval date
2016-02-07, 1394/11/18
Ethics committee reference number
IR.TUMS.REC.1394.1897

Health conditions studied

1

Description of health condition studied
Breast Cancer
ICD-10 code
C50
ICD-10 code description
malignant neoplasm of breast

Primary outcomes

1

Description
Limb lymph oedema volume
Timepoint
Before intervention and after ten sessions of treatment
Method of measurement
Using a volumeter, limb volume is measured by water displacement(mililiters)

2

Description
Limb circumference
Timepoint
Before intervention and after ten sessions of treatment
Method of measurement
by a tape (cm)

3

Description
Quality of Life
Timepoint
Before intervention and after ten sessions of treatment
Method of measurement
using of two questionnaires(QLQ-C30, QLQ-BR23)

Secondary outcomes

1

Description
Range of motion of shoulder joints
Timepoint
Before intervention and after ten sessions of treatment
Method of measurement
using a goniometer (degrees)

2

Description
Limb heaviness
Timepoint
Before intervention and after ten sessions of treatment
Method of measurement

Visual Analog Scale (cm or mm)

Intervention groups

1

Description
Treatments for intervention group (CDP+IPC) includes manual lymphatic drainage for 30 minutes in each session, multi-layer bandaging, exercise , skin and nail care and applicatin of intermittent penumatic compression device.Intermittent pressure is applied with a pressure about 40 mmHg for 30 minutes by using of IPC Lymphatron model 850 with six chambers.Special bandages which are known as short -stretch or low-stretch bandages are used in lymphedema bandage.This type of bandage is appropriate to reduce the size of swollen extremities physiologically, the probability of damage due to excessive pressure is very low. This bandage is used for 24 hours during the treatment phase. The bandage is done in figure of eight from distal to proximal in the affected limb.

Category
Rehabilitation

2

Description
Treatment for control group (CDP) includes manual lymphatic drainage for 30 minutes in each session, multi-layer bandaging, exercise and skin and nail care.Special bandages which are known as short -stretch or low-stretch bandages are used in lymphedema bandage.This type of bandage is appropriate to reduce the size of swollen extremities physiologically, the probability of damage due to excessive pressure is very low. This bandage is used for 24 hours during the treatment phase. The bandage is done in figure of eight from distal to proximal in the affected limb.

Category
Rehabilitation

Recruitment centers

1

Recruitment center

Name of recruitment center
Instittute of Mearaj cancer of Imam Khomeini Hospital

Full name of responsible person
Sepide Nafissi (MSc of Physiotherapy)

Street address
Iran-Tehran- End of Bolvar keshavarz-Imam Khomeini hospital

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Sponsors / Funding sources

1

Sponsor

Name of organization / entity
Deputy of research and technology of Tehran University of Medical Sciences

Full name of responsible person
Dr Masud Yunesian

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Tehran- Bolvar Keshavarz Avenue-Entrance of Ghods Ave-Central organisation of University,-Sixth Floor

City
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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
Deputy of research and technology of Tehran University of Medical Sciences

Proportion provided by this source
100

Public or private sector
empty

Domestic or foreign origin
empty

Category of foreign source of funding
empty

Country of origin

Type of organization providing the funding
empty

Person responsible for general inquiries

Contact

Name of organization / entity
Tehran Universaity of Medical Sciences, Faculty of Rehabilitation

Full name of responsible person
Miss Sepide Nafissi

Position
(MSc of Physiotherapy/ student of Doctor of Physiotherapy(DPT)

Other areas of specialty/work

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Sharing plan

Deidentified Individual Participant Data Set (IPD)
empty

Study Protocol
empty

Statistical Analysis Plan
empty

Informed Consent Form
empty

Clinical Study Report
empty

Analytic Code
empty

Data Dictionary
empty