

Clinical Trial Protocol

Iranian Registry of Clinical Trials

24 Jun 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

Hossein Bagheri

Name of organization / entity

Tehran University of Medical Sciences, Faculty of Rehabilitation

Country

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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 application of intermittent pneumatic 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

Institute 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

City

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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

Tehran

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 University 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