

# Clinical Trial Protocol

## Iranian Registry of Clinical Trials

25 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

Iran (Islamic Republic of)

##### Phone

+98 21 7753 3939

##### Email address

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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

Tehran

## 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

##### Street address

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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## Person responsible for scientific inquiries

### Contact

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## Person responsible for updating data

### Contact

**Name of organization / entity**

Tehran University of Medical Sciences, Faculty of Rehabilitation

**Full name of responsible person**

Hossein Bagheri

**Position**

Phd of physiotherapy

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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*