# Clinical Trial Protocol
# Iranian Registry of Clinical Trials

07 Nov 2026

## The effect of combined decongestive therapy and pneumatic compression pump on lymphedema indicators and body image in patients with lymphedema secondary to breast cancer treatment

## Protocol summary

**Summary**

Introduction: This study evaluated the effect of combined decongestive therapy (CDT) and pneumatic compression pump on lymphedema indicators in patients with lymphedema secondary to breast cancer treatment. Materials and methods: 42 women with breast cancer-related lymphedema participated. The volume difference of the upper limbs, upper limb circumference at 9 areas and shoulder joint range of motion were measured in all patients. Then they were divided randomly into an intervention (n=21) or control group (n=21). CDT in the intervention group was done in two phases. In the first phase CDT was performed with a compression pump for 4 weeks, 3 days per week. In the second phase, CDT was performed daily without a pump for 4 consecutive weeks by patients at home. At the end of each phase, the same primary measurements were done for both groups.

## General information

**Acronym**

CDT+ PCP

**IRCT registration information**

IRCT registration number: **IRCT138902212621N8**

Registration date: **2011-04-30, 1390/02/10**

Registration timing: **retrospective**

Last update:

Update count: **0**

**Registration date**

2011-04-30, 1390/02/10

**Registrant information**

**Name**

Marzieh Moattari

**Name of organization / entity**

Shiraz university of medical sciences

**Country**

Iran (Islamic Republic of)

**Phone**

+98 71 1647 4250

**Email address**

moattarm@sums.ac.ir

**Recruitment status**

**Recruitment complete**

**Funding source**

Vice chancellor for research, Shiraz university of medical sciences

**Expected recruitment start date**

2009-09-23, 1388/07/01

**Expected recruitment end date**

2010-01-21, 1388/11/01

**Actual recruitment start date**

empty

**Actual recruitment end date**

empty

**Trial completion date**

empty

**Scientific title**

The effect of combined decongestive therapy and pneumatic compression pump on lymphedema indicators and body image in patients with lymphedema secondary to breast cancer treatment

**Public title**

The effect of combined decongestive therapy and pneumatic compression pump on lymphedema indicators and body image in patients with lymphedema secondary to breast cancer treatment

**Purpose**

Treatment

**Inclusion/Exclusion criteria**

Inclusion criteria: 1.histoty of breast cancer, 2.history of surgery and chemotherapy and as needed hormone

therapy and radiotherapy, 3. affected by lymphedema (with degree of mild to severe) based on specialist diagnosis, 4. at least 1 year ago was undergone axillary node dissection, 5. do not have knowledge about combined decongestive therapy, 6. phone accessibility, 7. 35-70 years old. Exclusion criteria: 1. psychotic disorder, 2. existence sever pain at axillary area, 3. history of hysterectomy duo to uterus cancer, 4. severe cardiac disease, 5. heart failure, 6. renal failure, 7. severe hypertension, 8. existing other malignancies, 9. recurrent infection in arm, 10. musclo skeletal disease

**Age**
From **35 years** old to **70 years** old
**Gender**
Female

**Phase**
N/A
**Groups that have been masked**
*No information*
**Sample size**
Target sample size: **48**
**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**
Vice chancellor for research, Shiraz university of medical sciences
**Street address**
Zand St.
**City**
Shiraz
**Postal code**
71345-1978
**Approval date**
1990-01-01, 1368/10/11
**Ethics committee reference number**
CT-88-4919

## Health conditions studied

### 1

**Description of health condition studied**
postmastectomy lymphedema
**ICD-10 code**
I97.2
**ICD-10 code description**
Postmastectomy lymphoedema syndrome

## Primary outcomes

### 1

**Description**
differences in volume of both upper limbs
**Timepoint**
before the intervention, 4 and 8 weeks after that
**Method of measurement**
volumeter

### 2

**Description**
difference in circumference between the two upper limbs
**Timepoint**
before the intervention, 4 and 8 weeks after that
**Method of measurement**
meter

### 3

**Description**
shoulder joint range of motion
**Timepoint**
before the intervention, 4 and 8 weeks after that
**Method of measurement**
goniometer

### 4

**Description**
body image and relationships
**Timepoint**
before the intervention, 4 and 8 weeks after that
**Method of measurement**
body image and relationships scale (questionare)

## Secondary outcomes

### 1

**Description**
adduction motion of shoulder joint
**Timepoint**
before the intervention, 4 and 8 weeks after that
**Method of measurement**
goniometer

## Intervention groups

### 1

**Description**
Patients in in the control group received no treatment for lymphedema.

**Category**
N/A

**2**

**Description**
CDT in the intervention group was done in two phases. In the first phase CDT was performed with a compression pump for 4 weeks, 3 days per week. In the second phase, CDT was performed daily without a pump for 4 consecutive weeks by patients at home.
**Category**
Treatment - Devices

## Recruitment centers

**1**

**Recruitment center**
**Name of recruitment center**
Shahid Mottahari theraputic center
**Full name of responsible person**
Dr. Marzieh Moattari
**Street address**
Nemazi square, Zand St.
**City**
Shiraz

## Sponsors / Funding sources

**1**

**Sponsor**
**Name of organization / entity**
Shiraz university of medical sciences
**Full name of responsible person**
Dr. Dabbagh manesh
**Street address**
Vice chancellor for research center, Shiraz university of medical sciences, Zand St.
**City**
Shiraz
**Grant name**
**Grant code / Reference number**
CT-88-4919
**Is the source of funding the same sponsor organization/entity?**
Yes
**Title of funding source**
Shiraz 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**
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**Full name of responsible person**
Badri Jaafari
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## Person responsible for scientific inquiries

**Contact**
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## Person responsible for updating data

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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*