

Clinical Trial Protocol

Iranian Registry of Clinical Trials

24 Jun 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

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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.history 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 severe 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 therapeut center

Full name of responsible person

Dr. Marzieh Moattari

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Sponsors / Funding sources**1****Sponsor****Name of organization / entity**

Shiraz university of medical sciences

Full name of responsible person

Dr. Dabbagh manesh

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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**

Shiraz university of medical sciences

Full name of responsible person

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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