Clinical Trial Protocol
Iranian Registry of Clinical Trials

09 Nov 2026

The effect of ultrasound and Faradic under pressure on upper limb pain, swelling and function in patients with breast cancer after surgery

Protocol summary

Summary

The primary aim of this study is to investigate the effect of ultrasound and Faradic under pressure on upper limb pain, swelling and function in patients with breast cancer after surgery. In this study 45 patients participate who were randomly divided into three groups of 15 people. The first group receive conventional therapy (complex decongestive therapy) which includes four stages: gentle massage for lymph drainage, compression therapy with bandages, skin care and exercise. The second group, in addition to conventional therapy, receive ultrasound therapy with the intensity of 2 Watt / cm2 and with the frequency of 1 MHz in the arm, forearm and hand. The third group, in addition to conventional therapy, receive faradic under pressure flow. In all groups, measurements obtained by measuring the difference in volume between the two sides in various locations and measuring the difference between the volumes of fluid displacement, the pain using a scale to measure pain (numeric analog scale), and evaluate performance based on questionnaires DASH (Disability of Arm Shoulder Hand), those measured before treatment and after treatment.

General information

Acronym

IRCT registration information

IRCT registration number: **IRCT201310292391N14**
Registration date: **2016-01-03, 1394/10/13**
Registration timing: **prospective**

Last update:
Update count: **0**

Registration date

2016-01-03, 1394/10/13

Registrant information

Name

Zahra Rojhani Shirazi

Name of organization / entity

Shiraz University of Medical Sciences, School of Rehabilitation Sciences

Country

Iran (Islamic Republic of)

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+98 71 1627 1552

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Recruitment status

Recruitment complete

Funding source

Vice Chancellor for Research Affairs of Shiraz University of Medical Sciences

Expected recruitment start date

2016-01-09, 1394/10/19

Expected recruitment end date

2016-05-21, 1395/03/01

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

The effect of ultrasound and Faradic under pressure on upper limb pain, swelling and function in patients with breast cancer after surgery

Public title

The effect of electrotherapy modalities on pain and swelling in patients with breast cancer

Purpose

Treatment

Inclusion/Exclusion criteria

Inclusions criteria: Women with a history of breast cancer for at least the age of 18 ; for at least surgery and chemotherapy or surgery and radiation therapy ;

suffering lymph edema Exclusion criteria: Malignancies, including malignant lymph edema, bilateral breast cancer; Cancer or recurrent infection in the arm ; congenital lymph edema ; Patients who for other reasons such as trauma, burns, damage to lymph masses of the region have been affected by lymph edema.

Age
From **18 years** old

Gender
Female

Phase
N/A

Groups that have been masked
No information

Sample size
Target sample size: **45**

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
Shiraz University of Medical Sciences

Street address
Shiraz,1 street Abyverdy, School of Rehabilitation Sciences, ShiraUniversity of Medical Sciences, Department of Physical Therapy ,Chamran Boulevard

City
Shiraz

Postal code

Approval date
2015-09-23, 1394/07/01

Ethics committee reference number
ir.sums.rec.1394.167

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
pain

Timepoint
before treatment and after the tenth session

Method of measurement
numeric analog scale (NAS)

2

Description
swelling

Timepoint
before treatment and after the tenth session

Method of measurement
difference in volume between the two sides in various locations and measuring the difference between the volumes of fluid displacement

3

Description
function

Timepoint
before treatment and after the tenth session

Method of measurement
DASH questionnaires (Disability of Arm Shoulder Hand)

Secondary outcomes

empty

Intervention groups

1

Description
The first group receive conventional therapy (complex decongestive therapy) which includes four stages: gentle massage for lymph drainage, compression therapy with bandages, skin care and exercise.

Category
Treatment - Other

2

Description
The second group, in addition to conventional therapy, receive ultrasound therapy with the intensity of 2 Watt / cm2 and with the frequency of 1 MHz in the arm, forearm and hand.

Category
Other

3

Description
The third group, in addition to conventional therapy, receive faradic under pressure flow. (frequency 30 Hz, pulse width 300 microsecond, hold time 2 s, rest time 5

s,10 min on the flexors muscle of forearm and 10 min on the extensors muscle of forearm)

Category
Other

Recruitment centers

1

Recruitment center

Name of recruitment center
center of lymphedema motahari clinic

Full name of responsible person
Zahra Rojhani Shirazi

Street address

City
Shiraz

Sponsors / Funding sources

1

Sponsor

Name of organization / entity
Shiraz University of Medical Sciences

Full name of responsible person
Gholamreza Hatam

Street address
Shiraz Faculty of Rehabilitation, Chamran blvd.

City
Shiraz

Grant name

Grant code / Reference number

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
Zahra Rojhani Shirazi

Position
PhD

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