

Clinical Trial Protocol

Iranian Registry of Clinical Trials

07 Jul 2026

Determining the effect of massage and bandage on pain, edema and shoulder function after radical mastectomy

Protocol summary

Summary

This study is a randomized clinical trial conducted on 90 patients with breast cancer after radical mastectomy at oncology center of Imam Khomeini Hospital (Meraj and Central) to determine the effect of manual lymph massage and low pressure bandage on pain, edema and shoulder function. Massage and bandage were performed by therapist and family or patient for a 1 month period on the operated arm. Pain intensity, arm edema and shoulder function were measured and compared between groups.

General information

Acronym

IRCT registration information

IRCT registration number: **IRCT138810142983N1**
Registration date: **2011-05-14, 1390/02/24**
Registration timing: **registered_while_recruiting**

Last update:

Update count: **0**

Registration date

2011-05-14, 1390/02/24

Registrant information

Name

Reza Norouzadeh

Name of organization / entity

Shahed University

Country

Iran (Islamic Republic of)

Phone

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Email address

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Recruitment status

Recruitment complete

Funding source

Shahed University

Expected recruitment start date

2009-09-24, 1388/07/02

Expected recruitment end date

2011-08-24, 1390/06/02

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Determining the effect of massage and bandage on pain, edema and shoulder function after radical mastectomy

Public title

Determining the effect of massage and bandage on pain, edema and arm function after mastectomy surgery

Purpose

Prevention

Inclusion/Exclusion criteria

Inclusion criteria: breast cancer diagnosis, candidate for mastectomy with axillary lymphatic dissection, presence of an assistant for massage and bandage procedure
Exclusion criteria: Underlying disorders affecting limb (arm) or lymphatic system

Age

No age limit

Gender

Female

Phase

3

Groups that have been masked

No information

Sample size

Target sample size: **90**

Randomization (investigator's opinion)

Randomized

Randomization description
Blinding (investigator's opinion)

Not blinded

Blinding description**Placebo**

Not used

Assignment

Parallel

Other design features**Secondary Ids**

empty

Ethics committees**1****Ethics committee****Name of ethics committee**

Shahed University

Street address

Shahed University, Opposite Imam Khomeini Shrine,
Tehran-Qom Highway, Tehran

City

Tehran

Postal code**Approval date**

2009-02-21, 1387/12/03

Ethics committee reference number

37823

Health conditions studied**1****Description of health condition studied**

Radical Mastectomy

ICD-10 code

Z90.1

ICD-10 code description

Acquired absence of breast(s)

Primary outcomes**1****Description**

Lymphedema

Timepoint

first day after surgery and immediatly after end of
intervention(s)

Method of measurement

SPDI index

2**Description**

Pain severity

Timepoint

first day after surgery and immediatly after end of
intervention(s)

Method of measurement

SPDI index

3**Description**

Shoulder function

Timepoint

first day after surgery and immediatly after end of
intervention(s)

Method of measurement

SPDI index

Secondary outcomes

empty

Intervention groups**1****Description**

Daily Specialized massage on arm at operated side, each
massage session was at least 15 minutes

Category

Rehabilitation

2**Description**

Daily Specialized massage and low pressure bandage on
arm at operated side, each massage session was at least
15 minutes, bandage was kept at least 6 hours by the
patient

Category

Rehabilitation

3**Description**

No intervention

Category

N/A

Recruitment centers**1****Recruitment center****Name of recruitment center**

Imam khomeini Hospital, cancer institute

Full name of responsible person

Reza Norouzadeh

Street address

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Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Shahed University, Research Center

Full name of responsible person

Zahra Kiasalari

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Grant name**Grant code / Reference number****Is the source of funding the same sponsor organization/entity?**

Yes

Title of funding source

Shahed University, Research Center

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**

Shahed University Research Center

Full name of responsible person

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Position

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Position

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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