Clinical Trial Protocol
Iranian Registry of Clinical Trials

09 Nov 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

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Name of organization / entity
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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 Shrime, 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
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Tehran
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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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Shahed University, Opposite Imam Khomeini Shrime, Tehran-Qom Highway, Tehran
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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
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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