

# 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

+98 21 5522 8800

##### Email address

norouzadeh@shahed.ac.ir

##### 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 immediately after end of  
intervention(s)

#### Method of measurement

SPDI index

### 2

#### Description

Pain severity

#### Timepoint

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

## Method of measurement

SPDI index

### 3

#### Description

Shoulder function

#### Timepoint

first day after surgery and immediately 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

Tehran

##### City

Tehran

## Sponsors / Funding sources

## 1

### Sponsor

**Name of organization / entity**

Shahed University, Research Center

**Full name of responsible person**

Zahra Kiasalari

**Street address**

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

**City**

Tehran

**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**

Maryam Askari

**Position**

Midwife, MSN

**Other areas of specialty/work****Street address**

North Kargar Ave., Shahed University Research  
Center

**City**

Tehran

**Postal code**

1591715314

**Phone**

+98 21 6641 9772

**Fax****Email**

maya10sa@yahoo.com

**Web page address**

### Person responsible for scientific inquiries

**Contact****Name of organization / entity**

Shahed University

**Full name of responsible person**

Reza Norouzadeh

**Position**

MSN

**Other areas of specialty/work****Street address**

Rahimzadeh Alley, Valiasr Street, Shahed Nursing and  
Midwifery Faculty

**City**

Tehran

**Postal code**

1591715314

**Phone**

+98 216641858790

**Fax**

+98 21 6641 8580

**Email**

reza\_214@yahoo.comnorouzadeh@shahed.ac.ir

**Web page address**

### Person responsible for updating data

**Contact****Name of organization / entity**

Shahed University

**Full name of responsible person**

Reza Norouzadeh

**Position**

MSN, Faculty Member

**Other areas of specialty/work****Street address**

Valiasr Street

**City**

Tehran

**Postal code**

1591715314

**Phone**

+98 21 6641 8587

**Fax**

+98 21 6641 8580

**Email**

reza\_214@yahoo.comnorouzadeh@shahed.ac.ir

**Web page address**

### 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*