# Clinical Trial Protocol
# Iranian Registry of Clinical Trials

22 Nov 2026

## Effect of fibrin glue in seroma prevention after mastectomy

## Protocol summary

**Summary**

The aim of the study is to investigate the effect of fibrin glue in the prevention of Seroma after the mastectomy. In this study, 60 patients with Breast cancer are recruited from Imam Reza, Sina and Shams hospitals of Tabriz and randomly assigned into intervention or control group. The patients in the control group will undergo modified radical mastectomy with drain and the intervention group will undergo radical mastectomy and Lymphadenectomy and drain was fitted with fibrin glue injection of 2cc fibrin glue is in the axillary fossa. The drain is removed when daily discharge is less than 50cc are out. The patients will be visited four times in a month after the surgery and the presence of seroma in axillary area will be examined and if there is any seroma sonography will be done for the volume of seroma.

## General information

**Acronym**

**IRCT registration information**

IRCT registration number: **IRCT201010184511N7**
Registration date: **2010-10-26, 1389/08/04**
Registration timing: **registered_while_recruiting**

Last update:
Update count: **0**

**Registration date**

2010-10-26, 1389/08/04

**Registrant information**

**Name**

Farhang Parsafar

**Name of organization / entity**

Tabriz University of Medical Sciences

**Country**

Iran (Islamic Republic of)

**Phone**

+98 41 1334 1317

**Email address**

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**Recruitment status**

**Recruitment complete**

**Funding source**

Student Research Committee, Tabriz University of Medical Sciences

**Expected recruitment start date**

2010-06-22, 1389/04/01

**Expected recruitment end date**

2020-03-19, 1398/12/29

**Actual recruitment start date**

empty

**Actual recruitment end date**

empty

**Trial completion date**

empty

**Scientific title**

Effect of fibrin glue in seroma prevention after mastectomy

**Public title**

Effect of fibrin glue in seroma prevention after breast cancer

**Purpose**

Treatment

**Inclusion/Exclusion criteria**

Inclusion criteria: presence of breast cancer Exclusion criteria: Presence of any complications, Patient’s dissatisfaction

**Age**

No age limit

**Gender**

Female

**Phase**

N/A

**Groups that have been masked**

*No information*

**Sample size**

Target sample size: **60**

**Randomization (investigator's opinion)**
N/A
**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**
Tabriz University of Medical Sciences
**Street address**
Imam Reza Hospital, University St., Tabriz
**City**
Tabriz
**Postal code**
3345654387
**Approval date**
2010-06-10, 1389/03/20
**Ethics committee reference number**
12/22/ج

## 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**
Seroma
**Timepoint**
1 week
**Method of measurement**
examination- sonography

## Secondary outcomes

### 1

**Description**
Lymphedema
**Timepoint**
1 week
**Method of measurement**
Examination

## Intervention groups

### 1

**Description**
Control group: patients with breast cancer undergoing mastectomy and drainage
**Category**
Treatment - Surgery

### 2

**Description**
Intervention group: Patients with breast cancer undergoing mastectomy that fibrin glue were injected at the end of surgery and drains are built
**Category**
Treatment - Surgery

## Recruitment centers

### 1

**Recruitment center**
**Name of recruitment center**
Emamreza hospital
**Full name of responsible person**
Farhang parsafar
**Street address**
Imam Reza Hospital, University St., Tabriz
**City**
Tabriz

## Sponsors / Funding sources

### 1

**Sponsor**
**Name of organization / entity**
Student Research Committee, Tabriz University of Medical Sciences.
**Full name of responsible person**
Dr. Taghipur
**Street address**
Student Research Committee, Health and Nutrition department, Tabriz University of Medical Sciences, University St., Tabriz
**City**
Tabriz
**Grant name**
-
**Grant code / Reference number**
-
**Is the source of funding the same sponsor organization/entity?**
Yes

**Title of funding source**
Student Research Committee, Tabriz 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**
Tabriz University of Medical Sciences
**Full name of responsible person**
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**Position**
Surgery Assistant
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## Person responsible for scientific inquiries

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## Person responsible for updating data

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surgery assistant
**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*