

Clinical Trial Protocol

Iranian Registry of Clinical Trials

28 May 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)

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+98 41 1334 1317

Email address

parsafarf@tbzmed.ac.ir

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/ع

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

Farhang Parsafar

Position

Surgery Assistant

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

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Web page address**Person responsible for scientific inquiries****Contact****Name of organization / entity**

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Full name of responsible person

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Position

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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