

Clinical Trial Protocol

Iranian Registry of Clinical Trials

10 Jun 2026

Comparing the results of using a drain and not using a drain in mammoplasty patients with volume reduction of less than 500 cc

Protocol summary

Study aim

To determine the surgical outcome and complication rates in reduction mammoplasty with less than 500 cc resection, with and without the use of drains

Design

This trial has two intervention and control groups, which are randomly assigned to two groups of 13 people in a block design. All surgical procedures are the same for both groups, and the only difference is the use of a drain or not after surgery. This study is in phase 3

Settings and conduct

This study is a single-blind clinical trial that will be conducted at Hazrat Fatemeh Hospital in Tehran, Iran. All patients will undergo surgery using a standardized superomedial pedicle, short scar technique, with the only variable being drain use.

Participants/Inclusion and exclusion criteria

Inclusion Criteria: • Patients aged between 18 and 60 years. • Undergoing reduction mammoplasty with a resection volume of less than 500 cc per breast. • Body Mass Index (BMI) between 18 and 30 kg/m². • No history of breast pathology (e.g., benign or malignant tumors).
Exclusion Criteria: • Simultaneous performance of other surgical procedures on the breast. • Resection volume greater than 500 cc per breast. • History of underlying diseases such as uncontrolled diabetes, heart failure, or renal failure. • Active smokers or those with a history of smoking within the past 6 months. • History of bleeding disorders or current use of anticoagulant medications. • Previous history of radiotherapy or surgery involving the breast. • Presence of active infections or chronic wounds at the time of surgery.

Intervention groups

two groups: intervention Group (with drain placement after surgery) and Group control (without drain placement).

Main outcome variables

wound dehiscence, the total duration of healing and complete recovery (in days), hematoma, seroma,

postoperative infection

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20250824066966N1**

Registration date: **2025-09-23, 1404/07/01**

Registration timing: **registered_while_recruiting**

Last update: **2025-09-23, 1404/07/01**

Update count: **0**

Registration date

2025-09-23, 1404/07/01

Registrant information

Name

Alaa Aqel

Name of organization / entity

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Iran (Islamic Republic of)

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+98 21 8871 7272

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Recruitment status

recruiting

Funding source

Expected recruitment start date

2025-09-23, 1404/07/01

Expected recruitment end date

2026-06-21, 1405/03/31

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Comparing the results of using a drain and not using a drain in mammoplasty patients with volume reduction of less than 500 cc

Public title

Comparing the results of using a drain and not using a drain in mammoplasty

Purpose

Treatment

Inclusion/Exclusion criteria

Inclusion criteria:

Undergoing reduction mammoplasty with a resection volume of less than 500 cc per breast. Body Mass Index (BMI) between 18 and 30 kg/m² Good general health status (ASA Class I-II) No previous breast surgery No history of breast pathology (e.g., benign or malignant tumors)

Exclusion criteria:

Simultaneous performance of other surgical procedures on the breast Resection volume greater than 500 cc per breast. History of underlying diseases such as uncontrolled diabetes, heart failure, or renal failure. Active smokers or those with a history of smoking within the past 6 months History of bleeding disorders or current use of anticoagulant medications Previous history of radiotherapy or surgery involving the breast Presence of active infections or chronic wounds at the time of surgery Inability to comply with postoperative follow-up visits

Age

From 18 years old to 65 years old

Gender

Both

Phase

3

Groups that have been masked

- Outcome assessor

Sample size

Target sample size: 13

More than 1 sample in each individual

Number of samples in each individual: 2

Both breasts in an individual are counted as two samples, for which one person either has both breasts drained or is placed in the no-drain group

Randomization (investigator's opinion)

Randomized

Randomization description

the randomized block design method will be used. For this purpose, the sample size will be determined based on the online software and then, based on the code obtained from the block design analysis, one of the codes will be randomly selected in the operating room and assigned to the patients. Blocks of four participants will be created and two participants from each group will be placed in each block. Among the codes, one of the methods of using a drain and not using it will be selected for the patient

Blinding (investigator's opinion)

Double blinded

Blinding description

Postoperatively, patients will be monitored for seroma, hematoma, wound dehiscence, and infection using ultrasound and clinical assessment, and their data will be recorded. The person assessing the outcome and the person analyzing the data are blinded to the use or non-use of drains

Placebo

Not used

Assignment

Parallel

Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee

Ethics committee of Iran University of Medical Sciences

Street address

Hemmat highway

City

Tehran

Province

Tehran

Postal code

1234567890

Approval date

2025-08-13, 1404/05/22

Ethics committee reference number

IR.IUMS.REC.1404.492

Health conditions studied

1

Description of health condition studied

Mamoplasty

ICD-10 code

Z42.1

ICD-10 code description

Encounter for breast reconstruction following mastectomy

Primary outcomes

1

Description

hematoma

Timepoint

Three months after surgery

Method of measurement

Ultrasound

2

Description

Seroma

Timepoint

Three months after surgery

Method of measurement

Ultrasound

3

Description

Recovery Time

Timepoint

Three months after surgery

Method of measurement

Days

4

Description

wound dehiscence

Timepoint

Three months after surgery

Method of measurement

standard scale (0-2)

5

Description

Infection

Timepoint

Three months after surgery

Method of measurement

Observation

Secondary outcomes

empty

Intervention groups

1

Description

Intervention group: They will undergo surgery using the standard superomedial pedicle technique and short scar, and will use drains after surgery

Category

Treatment - Surgery

2

Description

Control group: They will undergo surgery using the standard superomedial pedicle technique and short scar, and will not use drains after surgery

Category

Treatment - Surgery

Recruitment centers

1

Recruitment center

Name of recruitment center

Hazrat Fatemeh Hospital

Full name of responsible person

Dr. Reza Vaghardoost

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Yousefabad, 21st avenue

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Sponsors / Funding sources

1

Sponsor

Name of organization / entity

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Full name of responsible person

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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

Iran University of Medical Sciences

Proportion provided by this source

100

Public or private sector

Public

Domestic or foreign origin

Domestic

Category of foreign source of funding

empty

Country of origin

Type of organization providing the funding

Academic

Person responsible for general inquiries

Contact

Name of organization / entity
Iran University of Medical Sciences
Full name of responsible person
Alaa Aqel
Position
Subspecialty assistant
Latest degree
Subspecialist
Other areas of specialty/work
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Sharing plan

Deidentified Individual Participant Data Set (IPD)

Yes - There is a plan to make this available

Study Protocol

Yes - There is a plan to make this available

Statistical Analysis Plan

Not applicable

Informed Consent Form

No - There is not a plan to make this available

Clinical Study Report

Not applicable

Analytic Code

Not applicable

Data Dictionary

Not applicable

Title and more details about the data/document

A pre-prepared checklist including patient demographic information such as age, gender, volume drained, seroma, hematoma, wound dehiscence rate, healing time, etc. will be performed; all this information will be shared after the study is completed

When the data will become available and for how long

One year after publication of the article, the original data will be available for use by other authors

To whom data/document is available

Researchers in the field of plastic surgery inside and outside Iran

Under which criteria data/document could be used

The use of data and documentation is permitted provided the authors' names are mentioned and the article is cited

From where data/document is obtainable

The author was emailed to obtain the data.
d.alaa.aqel@gmail.com

What processes are involved for a request to access data/document

First, the author will be sent an email, and after a week, if there is no response, a reminder will be sent, and the author will provide the documentation file to the requester after confirming their identity

Comments