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 mammaplasty with less than ۵۰۰ 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 ۱۸ and ۶۵ years. • Undergoing reduction mammaplasty with a resection volume of less than ۵۰۰ cc per breast. • Body Mass Index (BMI) between ۱۸ and ۳۰ 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 ۵۰۰ 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 ۶ 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 mammaplasty with a resection volume of less than ۵۰۰ cc per breast. Body Mass Index (BMI) between ۱۸ and ۳۰ 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 ۵۰۰ 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 ۶ 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 using 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
Street address
Yousefabad, 21st avenue
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Sponsors / Funding sources

1

Sponsor
Name of organization / entity
Iran University of Medical Sciences
Full name of responsible person
Majid safa
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1234567890
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Email
m.safa@iums.ac.ir
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