Clinical Trial Protocol
Iranian Registry of Clinical Trials

30 Jun 2026

The results of reduction mammoplasty in two superior and medial methods and their comparison

Protocol summary

Study aim
Comparing the results of reduction mammoplasty in two medial and superior methods and checking the sensation, blood supply and scar condition

Design
Two groups, one with the superior method and the other with the medial method. This double-blind trial will be randomized by block method, and parallel groups will be evaluated after examining and measuring sensation in the operated breast area, and the sensation, scar condition, and blood supply to the breast after surgery will be evaluated.

Settings and conduct
Before surgery, sensation measurement is done on both breasts of the patients. This work will be done using monofilament kit and TOPD test method. This work will be done in Hazrat Fatemeh Hospital and on all patients who are candidates for breast reduction surgery, and then the surgical method will be performed by randomizing into two groups with the superior and medial pedicle method, and after that, the sensation, scar condition, and blood supply condition will be measured again.

Participants/Inclusion and exclusion criteria
Inclusion criteria: women for reduction mammoplasty from 30 to 60 years old Patients who signed informed consent to enter the study Exclusion criteria: Patients who have already had breast surgery Patients with underlying or neurological diseases Patients with breast cancer

Intervention groups
It includes two groups of 16 people, the first group will be operated with the medial method and the second group with the superior method.

Main outcome variables
The degree of sensitivity in the areolar and skin and nipple, nipple blood supply condition, scar condition

General information

Reason for update

Acronym

IRCT registration information
IRCT registration number: **IRCT20230425057988N1**
Registration date: **2023-06-06, 1402/03/16**
Registration timing: **registered_while_recruiting**

Last update: **2023-06-06, 1402/03/16**
Update count: **0**

Registration date
2023-06-06, 1402/03/16

Registrant information
Name
Farzaneh Karami
Name of organization / entity
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Iran (Islamic Republic of)
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Recruitment status
Recruitment complete

Funding source

Expected recruitment start date
2023-05-05, 1402/02/15

Expected recruitment end date
2023-08-06, 1402/05/15

Actual recruitment start date
empty

Actual recruitment end date
empty

Trial completion date
empty

Scientific title

The results of reduction mammoplasty in two superior and medial methods and their comparison

Public title
Results of reduction mammoplasty in two different pedicle surgical methods
Purpose
Treatment
Inclusion/Exclusion criteria
Inclusion criteria:
Candidates for reduction mammoplasty Women between 30 and 60 years old Obtaining informed consent from patients
Exclusion criteria:
Patients who have already had breast surgery Patients with underlying or neurological diseases Patients with breast cancer
Age
From **30 years** old to **60 years** old
Gender
Female

Phase
N/A
Groups that have been masked

- Outcome assessor

Sample size
Target sample size: **32**
Randomization (investigator's opinion)
Randomized
Randomization description
Randomization is done by blocks method. For this purpose, blocks of four are prepared, the name of the intervention is written on two papers and the name of the comparison is written on the other two papers. The researcher knows that the intervention group is medial and the comparison group is superior. The papers are piled up and placed in the envelope, and one paper is pulled out for each patient. Then four papers are not returned to the envelope and this process is repeated until the sample volume is reached
Blinding (investigator's opinion)
Single blinded
Blinding description
One strain is blinded and the data and outcome assessor who records sensory results and other criteria after and before surgery is unaware of the type of surgery
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
۱۴۴۹۶۱۴۵۳۵
Approval date
2023-04-19, 1402/01/30
Ethics committee reference number
IR.IUMS.FMD.REC.1402.037

Health conditions studied

1

Description of health condition studied
Reduction Mammoplasty
ICD-10 code
Z41.1
ICD-10 code description
Encounter for cosmetic surgery

Primary outcomes

1

Description
میزان حساسیت
Timepoint
Before surgery and after surgery in the first, third and sixth month
Method of measurement
Using monofilament kit and tow point discrimination test method. In the monofilament method, this sensory test is performed by an evaluator in a standard way. Seven points on the chest are tested. These areas include one point in each quadrant (points 1 to 4), one point on the upper pole of the areola (point 5), one point on the lower pole of the areola (point 6), and one point on the nipple (point 7).

Secondary outcomes

1

Description
Scar status
Timepoint
One, three and six months after surgery
Method of measurement
Observing the absence of infection or swelling and redness at the scar site

2

Description
Blood supply status

Timepoint
One, three and six months after surgery
Method of measurement
Observing the condition of blood supply and lack of tissue necrosis and change of skin color to indigo or dark nipple based on clinic clinical examinations

Intervention groups

1

Description
Intervention group: In superior method surgery, we remove the skin in the superior pedicle area without touching the other parts and remove the skin from that area, and after the superior epithelialization, the skin is sutured
Category
Treatment - Surgery

2

Description
Control group: In medial surgery, the medial part is cut, and after tissue and fat removal, the skin is epithelialized and sutured at the incision site
Category
Treatment - Surgery

Recruitment centers

1

Recruitment center
Name of recruitment center
Hazrate Fatemeh Hospital
Full name of responsible person
Abolfazl Abbaszadeh
Street address
Seyed Jamalodin Asadabadi
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Sponsors / Funding sources

1

Sponsor
Name of organization / entity
Iran University of Medical Sciences
Full name of responsible person
Hossein Keyvani
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Grant name
Grant code / Reference number
Is the source of funding the same sponsor organization/entity?
No
Title of funding source
Hazrate Fatemeh Hospital
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
Farzaneh Karami
Position
Specialist Assistant
Latest degree
Specialist
Other areas of specialty/work
General Surgery
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Person responsible for scientific inquiries

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Position

Associate professor

Latest degree

Subspecialist

Other areas of specialty/work

Plastic and Reconstructive Surgery

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Sharing plan

Deidentified Individual Participant Data Set (IPD)

Yes - There is a plan to make this available

Study Protocol

Undecided - It is not yet known if there will be a plan to make this available

Statistical Analysis Plan

Not applicable

Informed Consent Form

Undecided - It is not yet known if there will be a plan to make this available

Clinical Study Report

Undecided - It is not yet known if there will be a plan to make this available

Analytic Code

Not applicable

Data Dictionary

Not applicable

Title and more details about the data/document

The data file of the patients and their characteristics will be made available to others if needed by the researchers by sending a request email, completely maintaining the confidentiality and non-identification of the individuals by assigning a code to each of them.

When the data will become available and for how long

It will be possible to access the consent form and patient information through the e-mail of the researcher and up to 1 year after the study. f.karami272@gmail.com

To whom data/document is available

Researchers and researchers in the field of plastic surgery in universities of medical sciences inside and outside the country

Under which criteria data/document could be used

In the case of ideas and examination of existing knowledge gaps in this subject, as well as modeling the implementation method and sub-goals of the research

From where data/document is obtainable

To receive documents, send a message to the author's email. f.karami272@gmail.com

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

Documents will be sent to applicants within 1 week after the email

Comments