

Clinical Trial Protocol

Iranian Registry of Clinical Trials

13 Jun 2026

The Effects of Reduction Mammoplasty and Mastopexy Surgeries on Inframammary Fold

Protocol summary

Study aim

The effects of reduction mammoplasty and mastopexy on infra-mammary fold

Design

Clinical trial with control group, with parallel groups, without blinding and without randomization on 50 patients

Settings and conduct

In this study, 50 female patients in Shahid Modarres Hospital in Tehran, after reduction mammoplasty and mastopexy, measured the changes in the inframammary fold in standing and bent forward positions and compared with before surgery.

Participants/Inclusion and exclusion criteria

Including : Patients who are candidates for surgery due to sagging and loose breasts Patients who are candidates for surgery due to breast deformity to breasts shaping Patients who are candidates for surgery due to the size of the breast to reduce the size and volume of the breast
Excluding: Breast asymmetry Existence of anomalies and deformities in the breasts Existence of anomalies and deformities in the breast wall Age<18 years old Breast Cancer Chemical therapy Addiction

Intervention groups

Intervention group: Patients undergoing mammoplasty. In this method, surgery is performed by anchoring incisions on the patient's breast using the superomedial pedicle technique, then it is repaired with Vicryl and PDS suture. In this group, the location of the inframammary fold (IMF) before and after surgery is assessed and the amount of displacement is measured. Control group: Patients undergoing mastopexy surgery. In this method, surgery is performed by anchoring incisions on the patient's breast using the superior and superomedial techniques, then it is repaired with Vicryl and PDS suture. In this group, the location of the inframammary fold (IMF) is also evaluated before and after surgery and the amount of displacement is measured.

Main outcome variables

The amount of inframammary fold (IMF) displacement postoperatively compared to preoperatively in standing and bent forward positions

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20200523047549N1**

Registration date: **2020-12-25, 1399/10/05**

Registration timing: **retrospective**

Last update: **2020-12-25, 1399/10/05**

Update count: **0**

Registration date

2020-12-25, 1399/10/05

Registrant information

Name

Feizollah Niazi

Name of organization / entity

Country

Iran (Islamic Republic of)

Phone

+98 21 2222 8956

Email address

feizollahniazi2015@sbmu.ac.ir

Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2019-11-16, 1398/08/25

Expected recruitment end date

2020-07-31, 1399/05/10

Actual recruitment start date

2019-11-16, 1398/08/25

Actual recruitment end date

2020-07-31, 1399/05/10
Trial completion date
2020-12-30, 1399/10/10
Scientific title
The Effects of Reduction Mammoplasty and Mastopexy Surgeries on Inframammary Fold

Public title
The Effects of Breast Surgeries on Inframammary Fold

Purpose
Treatment

Inclusion/Exclusion criteria

Inclusion criteria:

Patients who are candidates for surgery due to sagging and loose breasts
Patients who are candidates for surgery due to breast deformity to breasts shaping
Patients who are candidates for surgery due to the size of the breast to reduce the size and volume of the breast

Exclusion criteria:

Breast cancer
Age < 18 years old
Chemical therapy
Addiction
Breast asymmetry
Existence of anomalies and deformities in the breasts
Existence of anomalies and deformities in the breast wall

Age

From **18 years** old

Gender

Female

Phase

N/A

Groups that have been masked

No information

Sample size

Target sample size: **50**
More than 1 sample in each individual
Number of samples in each individual: **2**
Actual sample size reached: **50**
More than 1 sample in each individual
Actual sample size in each individual: **2**

Randomization (investigator's opinion)

Not randomized

Randomization description

Blinding (investigator's opinion)

Not blinded

Blinding description

Placebo

Not used

Assignment

Parallel

Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee

Ethics committee of Shahid Beheshti University of

Medical Sciences

Street address

Shahid Chamran Highway - Yemen St. - Shahid Arabi St. - Next to Ayatollah Taleghani Hospital - Shahid Beheshti University of Medical Sciences

City

Tehran

Province

Tehran

Postal code

1985717443

Approval date

2020-02-23, 1398/12/04

Ethics committee reference number

IR.SBMU.RETECH.REC.1398.838

Health conditions studied

1

Description of health condition studied

Inframammary fold location

ICD-10 code

L99

ICD-10 code description

Other disorders of skin and subcutaneous tissue in diseases classified elsewhere

Primary outcomes

1

Description

Displacement of the inframammary fold in a standing and bent position

Timepoint

Measurement of the location of the IMF at the beginning of the study, 1 month and 6 months after surgery

Method of measurement

Comparison of the distance between the crease below the breast and the crease in front of the elbow in standing and bent forward position (90 degrees) before and after mammoplasty and mastopexy

Secondary outcomes

empty

Intervention groups

1

Description

Intervention group: Patients undergoing mammoplasty. In this method, surgery is performed by anchoring incisions on the patient's breast using the superomedial pedicle technique, then it is repaired with Vicryl and PDS suture. In this group, the location of the inframammary fold (IMF) before and after surgery is assessed and the amount of displacement is measured.

Category

Treatment - Surgery

2

Description

Control group: Patients undergoing mastopexy surgery. In this method, surgery is performed by anchoring incisions on the patient's breast using the superior and superomedial techniques, then it is repaired with Vicryl and PDS suture. In this group, the location of the inframammary fold (IMF) is also evaluated before and after surgery and the amount of displacement is measured.

Category

Treatment - Surgery

Recruitment centers

1

Recruitment center

Name of recruitment center

Shahid Modarres Hospital

Full name of responsible person

Faizollah Niazi

Street address

Shahid Modarres Hospital, above Kaj Square

City

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Tehran

Postal code

1998734383

Phone

+98 21 2206 9355

Email

niazi_sf@yahoo.com

Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Shahid Beheshti University of Medical Sciences

Full name of responsible person

Feizollah Niazi

Street address

Shahid Modarres Hospital, Saadat Abad

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1998734383

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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

Shahid Beheshti 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

Shahid Beheshti University of Medical Sciences

Full name of responsible person

Fezollah Niazi

Position

Associate Professor

Latest degree

Subspecialist

Other areas of specialty/work

General Surgery

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Person responsible for scientific inquiries

Contact

Name of organization / entity

Shahid Beheshti University of Medical Sciences

Full name of responsible person

Feizollah Nniazi

Position

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Latest degree

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Person responsible for updating data**Contact****Name of organization / entity**

Shahid Beheshti University of Medical Sciences

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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

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

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

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

Data Dictionary

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

Title and more details about the data/document

After collecting information and analyzing it, the results will be published through the article.

When the data will become available and for how long

1 year

To whom data/document is available

main author and coresponder author

Under which criteria data/document could be used

In any case, the results will be published both negatively and positively.

From where data/document is obtainable

main author

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

The relevant request will be answered via email.

Comments