Clinical Trial Protocol
Iranian Registry of Clinical Trials

16 Sep 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
Tehran

Province
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

City
Tehran

Province
Tehran

Postal code
1998734383

Phone
+98 21 2206 9355

Email
niazi_sf@yahoo.com

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

Street address
Shahid Modarres Hospital, Saadat Abad

City
Tehran

Province
Tehran

Postal code
1998734383

Phone
+98 21 2206 9355

Email
niazi_sf@yahoo.com

Person responsible for scientific inquiries

Contact

Name of organization / entity
Shahid Beheshti University of Medical Sciences

Full name of responsible person
Feizollah Nniazi

Position
Associate Professor

Latest degree
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Other areas of specialty/work
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Shahid Modarres Hospital, Saadat Abad

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+98 21 2206 9355
Email
niazi_sf@yahoo.com

Person responsible for updating data

Contact
Name of organization / entity
Shahid Beheshti University of Medical Sciences
Full name of responsible person
Feizollah Niazi
Position
Associate Professor
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Other areas of specialty/work
General Surgery
Street address
Shahid Modarres Hospital, Saadat Abad
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Tehran
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niazi_sf@yahoo.com

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