Clinical Trial Protocol
Iranian Registry of Clinical Trials

17 Sep 2026

Comparing the aesthetic results of different types of umbilical cord reconstruction methods in abdominal operations: Mercedes incision versus inverted V incision in patients referred to Hazrat Fatemeh Hospital for umbilical cord reconstruction

Protocol summary

Study aim
Comparison of patients' and plastic surgeons' satisfaction with the aesthetic results of various types of umbilical reconstruction methods in abdominal operations: Mercedes incision in reverse V

Design
This study consists of two groups, in one group, the Mercedes surgery method is used, and the other one, the inverted V surgery method is used. There were 30 participants in each group and the method of blinding was a single-blind method, where the participant did not know about the surgical procedure and the researcher knew what the procedure was and what the results were like.

Settings and conduct
The research is carried out in Hazrat Fatima Hospital. Photographs are taken of patients before and three months after the operation so that the results of the operation can be compared. The patients are followed up for three months, and after that,they are surveyed and the level of satisfaction in terms of shape, size, and natural appearance is checked by them and ten surgical professors.

Participants/Inclusion and exclusion criteria
Inclusion criteria: Females over 18 years old and candidates for abdominoplasty surgery or breast reconstruction with abdominal flap/Exclusion criteria: no previous cosmetic surgery

Intervention groups
The first group in which the Mercedes method is used in such a way that a marking with methylene blue on the two lateral and upper wings between 0.5 and 1.0 cm from the central point is determined, forming the "Y" suggested in this technique. At this stage, the skin is cut above the Y mark. In the second group, in which the inverted V method is used, the arms of the cut are approximately 1.5 to 2 cm and an inverted V-shaped skin flap is raised at a predetermined, palpated umbilical point

Main outcome variables
The level of patient satisfaction; Complication rate; Aesthetic; The success rate of the operation

General information

Reason for update

Acronym

IRCT registration information
IRCT registration number: **IRCT20221111056465N1**
Registration date: **2023-02-20, 1401/12/01**
Registration timing: **registered_while_recruiting**

Last update: **2023-02-20, 1401/12/01**
Update count: **0**

Registration date
2023-02-20, 1401/12/01

Registrant information

Name
Vahab Rezaee

Name of organization / entity

Country
Iran (Islamic Republic of)

Phone
+98 21 8871 7272

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vahab_rezaee@yahoo.com

Recruitment status
Recruitment complete

Funding source

Expected recruitment start date

2023-02-19, 1401/11/30

Expected recruitment end date

2023-08-21, 1402/05/30

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Comparing the aesthetic results of different types of umbilical cord reconstruction methods in abdominal operations: Mercedes incision versus inverted V incision in patients referred to Hazrat Fatemeh Hospital for umbilical cord reconstruction

Public title

Comparison of aesthetic results of different types of umbilical reconstruction methods in abdominal operations: Mercedes incision versus inverted V incision

Purpose

Treatment

Inclusion/Exclusion criteria

Inclusion criteria:

People over 18 years old A candidate for Abdominoplasty or Breast Reconstruction Surgery Female

Exclusion criteria:

Performing navel cosmetic surgery in the past

Age

From **18 years** old to **50 years** old

Gender

Female

Phase

N/A

Groups that have been masked

- Participant
- Outcome assessor
- Data analyser

Sample size

Target sample size: **60**

Randomization (investigator's opinion)

Randomized

Randomization description

Simple randomization method is used in randomization. An envelope contains 60 pieces of paper on which groups A and B are written, and there are 30 pieces of each group in the envelope. Group A is assigned to the Mercedes surgery method and group B is assigned to the inverted V surgery method. Before performing the surgery, the surgeon takes out a paper from the envelope for each patient and the surgical method is selected based on the type of group

Blinding (investigator's opinion)

Single blinded

Blinding description

Before the operation, after choosing the type of operation, the surgeon and the researcher are aware of the type of operation, but after the surgery and subsequent examinations and data reporting, other residents of the center are used for examination, who are assigned a code for each type of operation. It is possible that only the researcher is aware of it

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

Seyed JamalodinAsadabadi St.

City

Tehran

Province

Tehran

Postal code

1433933111

Approval date

2023-02-08, 1401/11/19

Ethics committee reference number

IR.IUMS.FMD.REC.1401.644

Health conditions studied

1

Description of health condition studied

Patients referred for abdominoplasty and breast reconstruction with abdominal flap

ICD-10 code

Z42.1

ICD-10 code description

Encounter for breast reconstruction following mastectomy

Primary outcomes

1

Description

aesthetics evaluation

Timepoint

Three months after surgery

Method of measurement

Observation and direct question from the patient

Secondary outcomes

1

Description
Umbilical necrosis
Timepoint
Three months after surgery
Method of measurement
Direct observation

2

Description
mbilical stenosis
Timepoint
Three months after surgery
Method of measurement
Direct observation

Intervention groups

1

Description
Intervention group: In this group, the Mercedes surgical method is used, where a marking with methylene blue on the two lateral and upper wings between 0.5 and 1.0 cm from the central point is determined, and they form the "Y" suggested in this technique. At this point, the skin is cut above the Y mark. To prevent umbilical stenosis, two "cuts" are removed from the side flaps of the Y to allow the umbilical suture to fit better
Category
Treatment - Surgery

2

Description
Control group: In this group, we use the inverted V surgery method, where the arms of the incision are approximately 1.5 to 2 cm and are separated by a distance of approximately 1.5 to 2.5 cm at the base. An inverted V-shaped skin flap is raised at a predetermined, palpated umbilical point
Category
Treatment - Surgery

Recruitment centers

1

Recruitment center
Name of recruitment center
Hazrat Fatemeh Hospital
Full name of responsible person
Vahab Rezaee
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Sponsors / Funding sources

1

Sponsor
Name of organization / entity
Iran University of Medical Sciences
Full name of responsible person
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Tehran
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Email
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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
Vahab Rezaee
Position
Specialist assistant
Latest degree
Specialist
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
No - There is not a plan to make this available
Statistical Analysis Plan
Not applicable
Informed Consent Form
Yes - There is 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 written informed consent form will be provided to the participants after the procedure and will be included in the thesis. We have also published it in the Pajuheshyar system The data of the study also includes the results of the variables, including the level of satisfaction with the form of not causing complications
When the data will become available and for how long
The consent form will be placed in the attachments section after the thesis is printed. Also, the data of the participants is included in the thesis
To whom data/document is available
All people who have access to the full text of the thesis
Under which criteria data/document could be used
It can be modeled in similar studies
From where data/document is obtainable
Email to the general supervisor of the thesis Dr. Vahab Rezaee vahab_rezaee@yahoo.com
What processes are involved for a request to access data/document
After sending the email to the general supervisor, the thesis can be received within 1 week
Comments