

Clinical Trial Protocol

Iranian Registry of Clinical Trials

13 Jun 2026

A comparative clinical study of scars of surgical incisions between Monocryl versus Prolene (4-0) sutures for closing the outermost layer in mammoplasty

Protocol summary

Study aim

The aim of this study was to detect the superior suture material for Mammoplasty among Polypropylene and Monocryl, based on the comparison of the scars.

Design

Clinical trials for intervention, community-based and action-oriented, parallel group, double-blind

Settings and conduct

This study was carried out double-blind in Ghaem Hospital. The patient and doctor did not know which yarn was used on any side. The only person who knows which treatment is assigned to the left and right breast is the assistant professor of plastic surgery who has been collecting the analyst's information.

Participants/Inclusion and exclusion criteria

This clinical trial study was performed on 78 patients referred to surgery department of Ghaem Hospital during who were candidates for plastic mammoplasty surgery and patients were excluded for the following reasons: diabetes mellitus; anemia and hypertension because these disease affected on wound healing.

Intervention groups

Plastic surgery with Monocryl versus Prolene (4-0) sutures

Main outcome variables

Vancouver score; rate of infection and complications after surgery

General information

Reason for update

Acronym

-

IRCT registration information

IRCT registration number: **IRCT20171008036630N2**

Registration date: **2018-09-29, 1397/07/07**

Registration timing: **retrospective**

Last update: **2018-09-29, 1397/07/07**

Update count: **0**

Registration date

2018-09-29, 1397/07/07

Registrant information

Name

Ezatollah Rezaei

Name of organization / entity

Mashhad University of Medical Sciences

Country

Iran (Islamic Republic of)

Phone

+98 915 110 6392

Email address

rezaeie@mums.ac.ir

Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2015-09-21, 1394/06/30

Expected recruitment end date

2017-09-21, 1396/06/30

Actual recruitment start date

2015-09-21, 1394/06/30

Actual recruitment end date

2017-12-21, 1396/09/30

Trial completion date

2018-09-06, 1397/06/15

Scientific title

A comparative clinical study of scars of surgical incisions between Monocryl versus Prolene (4-0) sutures for closing the outermost layer in mammoplasty

Public title

A comparative clinical study of scars of surgical incisions between absorbed and non-absorbed sutures for closing

the outermost layer in mammoplasty

Purpose

Treatment

Inclusion/Exclusion criteria

Inclusion criteria:

All patients who were candidates for mammoplasty plastic surgery

Exclusion criteria:

Anemia Diabetes mellitus Hypertension

Age

No age limit

Gender

Female

Phase

N/A

Groups that have been masked

- Participant
- Investigator

Sample size

Target sample size: **78**

Actual sample size reached: **78**

Randomization (investigator's opinion)

Not randomized

Randomization description

Blinding (investigator's opinion)

Double blinded

Blinding description

This study was conducted double-blind. The general practitioner and the physician were not aware of which side was used on any of the threads. The only person who knows which treatment is assigned to the left and right breast is the assistant professor of plastic surgery who has been collecting the analyst's information.

Placebo

Not used

Assignment

Parallel

Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee

scientific committee and the institutional review board of Mashhad university of medical sciences

Street address

Ahmad Abad street

City

Mashhad

Province

Razavi Khorasan

Postal code

9177899191

Approval date

2018-01-20, 1396/10/30

Ethics committee reference number

IR.MUMS.fm.REC.1395.654

Health conditions studied

1

Description of health condition studied

Scars of surgical incisions

ICD-10 code

L00-L08

ICD-10 code description

Infections of the skin and subcutaneous tissue

Primary outcomes

1

Description

Repair of the skin after surgery

Timepoint

The first week, 1 and 3 months later

Method of measurement

Observer Scar Assessment (POSAS) criteria.

2

Description

The amount of inflammation of the wound

Timepoint

The first week, 1 and 3 months later

Method of measurement

Observer Scar Assessment (POSAS) criteria

3

Description

The degree of itching of the wound

Timepoint

The first week, 1 and 3 months later

Method of measurement

Observer Scar Assessment (POSAS) criteria.

Secondary outcomes

1

Description

satisfaction of patient

Timepoint

3 months after surgery

Method of measurement

based on Likert scale

Intervention groups

1

Description

Intervention group: One breast of all patients treated

with Monocryl (absorbable sutures catgut sutures 0-4 Weco Inc., China). Then patients are followed in the days and months mentioned (first week, 1 and 3 months later) and the photographer is done. All patients had a follow-up visit by two plastic surgeon blinded to the patient's study using Patient and Observer Scar Assessment Scale (POSAS) for one week , 1 and 3 months after the initial repair

Category

Treatment - Surgery

2

Description

Intervention group 2: other breast received polypropylene (nonabsorbable sutures 0-4 Weco Inc., China). Then patients are followed in the days and months mentioned (first week, 1 and 3 months later) and the photographer is done. All patients had a follow-up visit by two plastic surgeon blinded to the patient's study using Patient and Observer Scar Assessment Scale (POSAS) for one week , 1 and 3 months after the initial repair

Category

Treatment - Surgery

Recruitment centers

1

Recruitment center

Name of recruitment center

Ghaem haspital

Full name of responsible person

Ezatollah Rezaei

Street address

Ahmad Abad street

City

Mashhad

Province

Razavi Khorasan

Postal code

9177899191

Phone

+98 51 3801 2841

Fax

+98 51 3843 6199

Email

rezaeie@mums.ac.ir

Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Mashhad University of Medical Sciences

Full name of responsible person

Ezatollah Rezaei

Street address

Ahmad Abad street

City

Mashhad

Province

Razavi Khorasan

Postal code

9177899191

Phone

+98 51 3801 2841

Fax

+98 51 3843 6199

Email

rezaeie@mums.ac.ir

Grant name

Grant code / Reference number

Is the source of funding the same sponsor organization/entity?

Yes

Title of funding source

Mashhad 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

Mashhad University of Medical Sciences

Full name of responsible person

Ezatollah Rezaei

Position

Associate professor

Latest degree

Subspecialist

Other areas of specialty/work

General Surgery

Street address

Ahmad abad street

City

mashhad

Province

Razavi Khorasan

Postal code

9177899191

Phone

+98 51 3801 2840

Email

rezaeie@mums.ac.ir

Person responsible for scientific inquiries

Contact

Name of organization / entity

Mashhad University of Medical Sciences

Full name of responsible person

Ezatollah Rezaei

Position

Associate professor

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Phone

+98 51 3801 2841

Email

rezaeie@mums.ac.ir

Sharing plan**Deidentified Individual Participant Data Set (IPD)**

No - There is not a plan to make this available

Justification/reason for indecision/not sharing IPD

No more information

Study Protocol

Undecided - It is not yet known if there will be 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

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

Mashhad University of Medical Sciences

Full name of responsible person

Ezatollah Rezaei

Position

Associate professor

Latest degree

Subspecialist

Other areas of specialty/work

General Surgery

Street address