

# 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

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Ahmad Abad street

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**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

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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**

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

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Mashhad University of Medical Sciences

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**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****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