Clinical Trial Protocol
Iranian Registry of Clinical Trials

18 Sep 2026

Investigating the effect of flap fixation with MONOCRYLE suture after mastectomy in seroma formation in breast cancer patients

Protocol summary

Study aim

Incidence of seroma formation after flap fixation with MONOCRYLE suture in mastectomy

Design

Sample collection during 12 months was selected from clients for surgery. To determine the sample size, the sample volume formula based on power was used. The sample size in each group was 62 people. The study is a blind and the mastectomy will be performed in the usual way and the mastectomy with flap fixation will be performed with a monocrystalline suture. Patients will be randomly divided into intervention and control groups.

Settings and conduct

Patient information is recorded and discharged during the first, second and third day of hospitalization after surgery The inside of the drone bag was measured accurately daily and in case of volume less than 30 ml daily, drain will come out. The number of days of treatment for each patient will be recorded in the data collection form. Then Patients will be discharged within three days, regardless of the presence or absence of the disease. Since the Withdrawal of the drain until fourteen days later Probable seromas will be carefully examined and evaluated in the area of operation. Information Patients with seroma are recorded with the amount they need to evacuateIf necessary, it will be emptied.

Participants/Inclusion and exclusion criteria

All of breast cancer patients who are candidate mastectomy

Intervention groups

Patients in the intervention group are who had flap fixation with MONOCRYLE suture after mastectomy in breast cancer

Main outcome variables

Seroma formation; infection; pain; limited mobility; wound opening

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20200510047379N1**
Registration date: **2021-09-12, 1400/06/21**
Registration timing: **retrospective**

Last update: **2021-09-12, 1400/06/21**
Update count: **0**

Registration date

2021-09-12, 1400/06/21

Registrant information

Name

Leyla Shojaee

Name of organization / entity

Country

Iran (Islamic Republic of)

Phone

+98 11 3321 9579

Email address

l.shojaei@mazums.ac.ir

Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2020-01-21, 1398/11/01

Expected recruitment end date

2021-03-05, 1399/12/15

Actual recruitment start date

2020-01-21, 1398/11/01

Actual recruitment end date

2021-03-05, 1399/12/15

Trial completion date

2021-03-19, 1399/12/29

Scientific title

Investigating the effect of flap fixation with MONOCRYLE suture after mastectomy in seroma formation in breast cancer patients

Public title
Seroma formation after mastectomy with flap fixation using MONOCRYLE suture in breast cancer patients
Purpose
Treatment
Inclusion/Exclusion criteria
Inclusion criteria:
All breast cancer patients who are candidates for mastectomy
Exclusion criteria:
Diabetes Use of Corticosteroid
Age
No age limit
Gender
Both

Phase
N/A
Groups that have been masked

- Participant

Sample size
Target sample size: **124**
Actual sample size reached: **120**
Randomization (investigator's opinion)
Not randomized
Randomization description
Blinding (investigator's opinion)
Single blinded
Blinding description
Participants in this study will enter the intervention and control groups non-randomly after obtaining informed consent and will not be aware of the type of intervention.
Placebo
Not used
Assignment
Other
Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee
Name of ethics committee
Ethics committee of Imam Khomeini hospital of Sari, Mazandaran University of Medical Sciences
Street address
Amir-Mazandarani St.
City
Sari
Province
Mazandaran
Postal code
4816633131
Approval date
2019-12-25, 1398/10/04
Ethics committee reference number
IR.MAZUMS.IMAMHOSPITAL.REC.1398.147

Health conditions studied

1

Description of health condition studied
Seroma formation in breast cancer surgery
ICD-10 code
L76
ICD-10 code description
Intraoperative and postprocedural complications of skin and subcutaneous tissue

Primary outcomes

1

Description
Seroma formation
Timepoint
Days 3,7,14 after surgery
Method of measurement
Check the volume of secretions collected in the drain located at the site of operation

2

Description
Wound infection
Timepoint
Days 3,7,14 after surgery
Method of measurement
Wound observing and investigating the wound for local and systemic symptoms

3

Description
Wound opening
Timepoint
Days 3,7,14 after surgery
Method of measurement
Observing the wound

4

Description
Pain in wound
Timepoint
Days 3,7,14 after surgery
Method of measurement
Asking patient

5

Description
Limitation of mobility of limbs in site of wound
Timepoint

Days 3,7,14 after surgery

Method of measurement

Examination of patients' limb mobility

Secondary outcomes

empty

Intervention groups

1

Description

Intervention group: In this group of breast mastectomy patients, after removing the flap, the flap will be connected to the pectoralis muscle in several rows using MONOCRYL suture (manufactured by SMI AG).

Category

Treatment - Surgery

2

Description

Control group: In this group of breast mastectomy patients, after removing the flap, the flap will be connected to the pectoralis muscle in several rows using conventional sutures.

Category

Treatment - Surgery

Recruitment centers

1

Recruitment center

Name of recruitment center

Imam Khomeini hospital

Full name of responsible person

Leyla Shojaee

Street address

Amir-Mazandarani

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4816633131

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Email

shojaeeleyla@yahoo.com

Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Mazandaran University of Medical Sciences

Full name of responsible person

Majid Saeedi

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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

Mazandaran University of Medical Sciences

Proportion provided by this source

60

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

Mazandaran University of Medical Sciences

Full name of responsible person

Leyla Shojaee

Position

Assistant Professor

Latest degree

Subspecialist

Other areas of specialty/work

General Surgery

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Person responsible for scientific

inquiries

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Position
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Person responsible for updating data

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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
Yes - There is 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
The data were read only to include unidentifiable individual profiles and main outcomes based on a reasonable request.

When the data will become available and for how long
The data will be available after publication.

To whom data/document is available
Researchers working in academic institutions and surgeons can access the data upon reasonable request.

Under which criteria data/document could be used
The data can be used for review and validation upon request.

From where data/document is obtainable
Dr. Leyla Shojaee, Imam Khomeini Hospital of Sari

What processes are involved for a request to access data/document
To request the data, an email stating the reasons will be sent to the person in charge of the clinical trial and after their approval, the data will be available.

Comments