

Clinical Trial Protocol

Iranian Registry of Clinical Trials

27 Jul 2026

The effects of topical phenytoin solution on the drainage serous fluid modified radical mastectomy in patients with breast cancer

Protocol summary

Summary

The aim of this study was to determine the effect of topical phenytoin solution on serous fluid drainage modified radical mastectomy in patients with breast cancer and duration drains to patients and its impact on reducing the incidence of seroma formation. Inclusion: All patients with breast cancer undergoing modified radical mastectomy ; without a history of allergy to phenytoin ; without comorbidities. Exclusion criteria: patients who are not surgical; have a history of comorbidities; have a history of allergy to phenytoin. Double-blind study in 31 patients performed. For placebo of saline used. Time intervention drains and close skin solution is injected through the drain. The expected results are reducing the amount of fluid and seroma formation in the future.

General information

Acronym

IRCT registration information

IRCT registration number: **IRCT201601111786N6**

Registration date: **2016-01-29, 1394/11/09**

Registration timing: **retrospective**

Last update:

Update count: **0**

Registration date

2016-01-29, 1394/11/09

Registrant information

Name

Nasrin Rahmani

Name of organization / entity

Mazandaran University of Medical Sciences

Country

Iran (Islamic Republic of)

Phone

+98 15 1226 1700

Email address

nrahmani@mazums.ac.ir

Recruitment status

Recruitment complete

Funding source

Mazandaran University of Medical Sciences

Expected recruitment start date

2014-06-22, 1393/04/01

Expected recruitment end date

2015-06-22, 1394/04/01

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

The effects of topical phenytoin solution on the drainage serous fluid modified radical mastectomy in patients with breast cancer

Public title

Topical Solution phenytoin effect on fluid after breast cancer surgery

Purpose

Treatment

Inclusion/Exclusion criteria

Inclusion: All patients with breast cancer undergoing modified radical mastectomy ; without a history of allergy to phenytoin ; without comorbidities. Exclusion criteria: patients who are not surgical; have a history of comorbidities; have a history of allergy to phenytoin

Age

No age limit

Gender

Female

Phase

N/A

Groups that have been masked

No information

Sample size

Target sample size: 31

Randomization (investigator's opinion)

Randomized

Randomization description

Blinding (investigator's opinion)

Double blinded

Blinding description

Placebo

Used

Assignment

Parallel

Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee

Mazandaran University of Medical Sciences

Street address

, The Imam Khomeini three ways Jouybar, the beginning of the highway Valieasr, Mazandaran University of Medical Sciences

City

Sari

Postal code

4817844718

Approval date

2015-07-05, 1394/04/14

Ethics committee reference number

IR.MAZUMS REC.94

Health conditions studied

1

Description of health condition studied

breast cancer

ICD-10 code

C50

ICD-10 code description

Malignant neoplasm of breast

Primary outcomes

1

Description

DRAIN SECTRETION

Timepoint

first second and third day after surgery

Method of measurement

cc per 24 hours

2

Description

The number of days to drain

Timepoint

The day after surgery to drain down time

Method of measurement

day

3

Description

seroma formation

Timepoint

14 days after discharge

Method of measurement

clinical examination

Secondary outcomes

1

Description

seroma formation

Timepoint

14 days after discharge

Method of measurement

clinical examination

2

Description

The remaining drain time

Timepoint

The first day after surgery to drain down time

Method of measurement

day

Intervention groups

1

Description

15 ml of Phenytoin solution1% injected through the drain at the first day after surgery

Category

Treatment - Drugs

2

Description

In the control group 15cc of normal saline injected through drain at the first day after surgery.

Category

Placebo

Recruitment centers

1

Recruitment center

Name of recruitment center

Imam Khomeini Hospital in Sari
Full name of responsible person
Dr.N Rahmani
Street address
Imam Khomeini Hospital in Sari
City
Sari

Sponsors / Funding sources

1

Sponsor

Name of organization / entity
Mazandaran University of Medical Sciences
Full name of responsible person
Dr.R Esmaeili
Street address
Imam (RA) three ways Jooybar, the beginning of the
highway Valieasr, Mazandaran University of Medical
Sciences
City
Sari

Grant name
10506

Grant code / Reference number
1294502

**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
100

Public or private sector
empty

Domestic or foreign origin
empty

Category of foreign source of funding
empty

Country of origin

Type of organization providing the funding
empty

Person responsible for general inquiries

Contact

Name of organization / entity
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Full name of responsible person
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Person responsible for updating data

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Sharing plan

Deidentified Individual Participant Data Set (IPD)

empty

Study Protocol

empty

Statistical Analysis Plan

empty

Informed Consent Form

empty

Clinical Study Report

empty

Analytic Code

empty

Data Dictionary
empty