Clinical Trial Protocol
Iranian Registry of Clinical Trials

22 Nov 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 formationInclusion: All patients with breast cancer undergoing modified radical mastectomy ; without a history of allergy to phenytoin ; without comorbodities 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 comorbodities 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
Mazandaran University of medical science

Full name of responsible person
Dr.H Karimi

Position
general surgery resident

Other areas of specialty/work

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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