

# Clinical Trial Protocol

## Iranian Registry of Clinical Trials

09 Jun 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 solution 1% 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**  
**Street address**  
Imam Khomeini Hospital of Sari  
**City**  
Sari  
**Postal code**  
**Phone**  
+98 11 3336 1700  
**Fax**

**Email**  
NRahmani@mazums.ac.ir  
**Web page address**

## Person responsible for scientific inquiries

#### Contact

**Name of organization / entity**  
Mazandaran University of medical science  
**Full name of responsible person**  
Dr.N Rahmani  
**Position**  
Assistant Professor  
**Other areas of specialty/work**  
**Street address**  
Imam Khomeini Hospital of Sari  
**City**  
Sari  
**Postal code**  
**Phone**  
+98 11 3336 1700  
**Fax**  
**Email**  
NRahmani@mazums.ac.ir  
**Web page address**

## Person responsible for updating data

#### Contact

**Name of organization / entity**  
Mazandaran University of medical science  
**Full name of responsible person**  
Dr.S Namazi Baigi  
**Position**  
general surgery resident  
**Other areas of specialty/work**  
**Street address**  
Imam Khomeini Hospital in Sari  
**City**  
Sari  
**Postal code**  
**Phone**  
+98 11 3336 1700  
**Fax**  
**Email**  
dr.s.namazi.gsurgeon@gmail.com  
**Web page address**

## 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*