

# Clinical Trial Protocol

## Iranian Registry of Clinical Trials

18 Jun 2026

### Prophylactic & therapeutic effects of topical phenytoin administration on radiation induced dermatitis in breast cancer patients

#### Protocol summary

##### Summary

Objectives: Phenytoin has been known to be effective in wound healing processes. In this clinical trial we aim to evaluate its efficacy in radiotherapy induced dermatitis. Design: Fifty female patients with breast cancer at Babolsar's Shahid-Rajaei hospital, with indication of radiotherapy after modified radical mastectomy (Inclusion criteria), would be allocated in 2 groups (control and test). Setting and conduct: Patients with diabetes mellitus, collagen vascular, concurrent chemotherapy, or history of chest wall radiation would be excluded from the study (Exclusion criteria). Patients would be randomly allocated in each 2 groups and would receive either phenytoin 1% or ointment base (petrolatum). The ointments would be applied on the chest wall (region of radiotherapy) 2 times daily. The target area would be washed with a neutral soap (Dove (R)) every time before radiation therapy. The radiotherapy induced acute dermatitis would be scored weekly according to RTOG (Radiation Therapy Oncology Group) criteria by a radiation oncologist (Main Outcome measures).

#### General information

##### Acronym

##### IRCT registration information

IRCT registration number: **IRCT2012070710205N1**

Registration date: **2013-06-01, 1392/03/11**

Registration timing: **retrospective**

Last update:

Update count: **0**

##### Registration date

2013-06-01, 1392/03/11

##### Registrant information

Name

Dariush Moslemi

##### Name of organization / entity

Babol University of Medical Sciences

##### Country

Iran (Islamic Republic of)

##### Phone

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##### Email address

d.moslemi@mubabol.ac.ir

##### Recruitment status

**Recruitment complete**

##### Funding source

Vice chancellor for Research, Babol University of Medical Sciences

##### Expected recruitment start date

2012-09-22, 1391/07/01

##### Expected recruitment end date

2013-03-15, 1391/12/25

##### Actual recruitment start date

empty

##### Actual recruitment end date

empty

##### Trial completion date

empty

##### Scientific title

Prophylactic & therapeutic effects of topical phenytoin administration on radiation induced dermatitis in breast cancer patients

##### Public title

Phenytoin application in radiation induced dermatitis

##### Purpose

Treatment

##### Inclusion/Exclusion criteria

Inclusion criteria: Patients with first occurrence of breast cancer Exclusion criteria: Patients with concurrent chemoradiation; diabetes; collagen-vascular diseases; history of radiotherapy

##### Age

From **16 years** old

**Gender**

Female

**Phase**

2

**Groups that have been masked**

*No information*

**Sample size**

Target sample size: **50**

**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**

Babol University of Medical Sciences' Ethics Committee

**Street address**

Ganje-Afrouz St.

**City**

Babol

**Postal code**

4717641367

**Approval date**

2012-09-09, 1391/06/19

**Ethics committee reference number**

7074 /30/ز/پ

**Health conditions studied**

1

**Description of health condition studied**

Breast Cancer

**ICD-10 code**

C50.0

**ICD-10 code description**

Malignant neoplasm of breast

**Primary outcomes**

1

**Description**

Dermatitis

**Timepoint**

Weekly

**Method of measurement**

According to RTOG scoring system

**Secondary outcomes**

1

**Description**

Local adverse reactions

**Timepoint**

weekly

**Method of measurement**

physical exam

**Intervention groups**

1

**Description**

Intervention (Phenytoin topical ointment): Patients undergoing radiotherapy will receive Phenytoin ointment BD, for 25 sessions (5 days/week)

**Category**

Treatment - Drugs

2

**Description**

Control (Placebo/ ointment base): Patients undergoing radiotherapy will receive petrolatum ointment BD, for 25 sessions (5 days/week)

**Category**

Placebo

**Recruitment centers**

1

**Recruitment center**

**Name of recruitment center**

Babolsar-Shahid Rajaei Hospital

**Full name of responsible person**

Dr Dariush Moslemi

**Street address**

Shariatee St,

**City**

Babolsar

**Sponsors / Funding sources**

1

**Sponsor**

**Name of organization / entity**

Vice Chancellor for Research and Technology, Babol University of Medical Sciences

**Full name of responsible person**

Dr Ali Bijani

**Street address**

Vice Chancellor for Research and Technology; Babol  
University of Medical Sciences; Ganje-Afroz St.

**City**

Babol

**Grant name**

**Grant code / Reference number**

**Is the source of funding the same sponsor  
organization/entity?**

Yes

**Title of funding source**

Vice Chancellor for Research and Technology, Babol  
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**

Vice Chancellor for Research and technology, Babol  
University of Medical Sciences

**Full name of responsible person**

Ebrahim Zabihi

**Position**

Lecturer, Academic staff

**Other areas of specialty/work**

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**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*