Clinical Trial Protocol
Iranian Registry of Clinical Trials

15 Nov 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. Deign: Fifty female patients with breast cancer at Babolsar's Shahid-Rajaee 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)

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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 Rajaee 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 Scenices

Full name of responsible person
Dr Ali Bijani

Street address

Vice Chancellor for Research and Technology; Babol University of Medical Sciences; Ganje-Afrooz 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 Scenices

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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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