Clinical Trial Protocol
Iranian Registry of Clinical Trials

08 Nov 2026

Prophylactic and therapeutic effects of Recove Ointment on radiation induced dermatitis in breast cancer patients

Protocol summary

Summary
Sixty patients with breast cancer at Babolsar's Shahid-Rajaee hospital, with indication of radiotherapy after modified radical mastectomy, would be allocated in 2 groups (control and test). Patients with diabetes mellitus, collagen vascular, concurrent chemotherapy, or history of chest wall radiation would be excluded from the study. Patients would be randomly allocated in each 2 groups and would receive either Recove 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 according the RTOG (Radiation Therapy Oncology Group) criteria by a radiation oncologist.

General information

Acronym
IRCT registration information
IRCT registration number: **IRCT201204047136N2**
Registration date: **2013-01-27, 1391/11/08**
Registration timing: **registered_while_recruiting**

Last update:
Update count: **0**
Registration date
2013-01-27, 1391/11/08

Registrant information
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Recruitment status
Recruitment complete
Funding source
Deputy of Research and technology-Babol University of Medical Sciences-

Expected recruitment start date
2012-08-05, 1391/05/15
Expected recruitment end date
2013-03-05, 1391/12/15
Actual recruitment start date
empty
Actual recruitment end date
empty
Trial completion date
empty

Scientific title
Prophylactic and therapeutic effects of Recove Ointment on radiation induced dermatitis in breast cancer patients

Public title
Prophylactic and therapeutic effects of Recove Ointment on radiation induced dermatitis in breast cancer patients
Purpose
Treatment
Inclusion/Exclusion criteria
Inclusion criteria: having diagnosed as having breast cancer; indication of radiotherapy and already underwent modified radical mastectomy. Exclusion criteria: Diabetes mellitus; Collagen vascular diseases; concurrent chemotherapy and history of chest wall radiation therapy.
Age
No age limit
Gender
Female

Phase
2
Groups that have been masked
No information
Sample size
Target sample size: **60**
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
Street address
Ganje-Afrouz St.
City
Babol
Postal code
Approval date
2012-07-30, 1391/05/09
Ethics committee reference number
6830/30/ژ/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 reaction
Timepoint
weekly
Method of measurement
physical exam

Intervention groups

1

Description
Intervention (Recove(R) topical ointment): Patients undergoing radiotherapy will receive Recove 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
City
Babolsar

Sponsors / Funding sources

1

Sponsor
Name of organization / entity
Deputy of Research and Technology- Babol University of Medical Scenices
Full name of responsible person
Dr Ali Bijani
Street address
Research and Development office
City
Babol
Grant name
Grant code / Reference number
Is the source of funding the same sponsor

organization/entity?
Yes
Title of funding source
Deputy of 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

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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