

Clinical Trial Protocol

Iranian Registry of Clinical Trials

18 Sep 2026

The study of radioprotective effects of topical atorvastatin gel on skin toxicity in breast cancer radiotehrapy: a double-blind randomized, placebo- controlled clinical trial

Protocol summary

Summary

The aim of this study is to evaluate the radioprotective effect of atorvastatin topical drug on acute radiation dermatitis induced by ionizing radiation in patients with breast cancer. This study is a double blind randomized, placebo-controlled clinical trial. This study will be performed on sixty patients with breast cancers that will admit to Radiotherapy Center in Imam Khomeini Hospital in Sari, Iran. Inclusion criteria are patients with breast cancer after surgery with ages 18-60 years old. Exclusion criteria are patients with liver, kidney injuries and with acute dermatitis and take anti-inflammatory and corticosteroids drugs. Patients will receive atorvastatin topical drug or placebo two times per day (BD) during radiotherapy fractions. Drug or placebo administration will be continued end of radiotherapy in patients. Severity of skin side effects will be visited and recorded in questioners' forms according to RTOG criteria during this study weekly, these parameters are dermatitis, etyma, wound, scare, pain and inching. The results of atorvastatin and placebo groups will be compared.

General information

Acronym

IRCT registration information

IRCT registration number: **IRCT2016062219423N2**
Registration date: **2016-07-20, 1395/04/30**
Registration timing: **prospective**

Last update:

Update count: **0**

Registration date

2016-07-20, 1395/04/30

Registrant information

Name

Seyed Jalal Hosseinimehr

Name of organization / entity

Mazandaran University of Medical Sciences

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Recruitment status

Recruitment complete

Funding source

Mazandaran University of Medical Sciences

Expected recruitment start date

2016-09-22, 1395/07/01

Expected recruitment end date

2017-09-23, 1396/07/01

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

The study of radioprotective effects of topical atorvastatin gel on skin toxicity in breast cancer radiotehrapy: a double-blind randomized, placebo-controlled clinical trial

Public title

The study of radioprotective effects of topical atorvastatin gel on skin toxicity in breast cancer radiotehrapy: a double-blind randomized, placebo-controlled clinical trial

Purpose

Prevention

Inclusion/Exclusion criteria

Inclusion criteria: Adults over 18 years and less 70 years; breast cancer; about 50Gy total dose of radiation.
Exclusion criteria: Smoking; using the anti-inflammatory drug such as dexametasone and NSAID; active skin infection and dermatitis; using any topical products on breast; the disease weakens related to the immune system and a lack of diabetes that affected on wound healing; diseases related to kidney and liver.

Age

From **18 years** old to **60 years** old

Gender

Female

Phase

2-3

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

Ethical Committee of Mazandaran University of Medical Sciences

Street address

Vice Chancellor for Research and Technology,
Mazandaran University of Medical Sciences, Molam Sq

City

Sari

Postal code

Approval date

2016-06-05, 1395/03/16

Ethics committee reference number

IR.MAZUMS.REC.95-2159

Health conditions studied

1

Description of health condition studied

Radiodermatitis

ICD-10 code

C50, L58

ICD-10 code description

Malignant neoplasm of breast, Acute radiodermatitis

Primary outcomes

1

Description

Severity of radiation-induced skin toxicity (such as Erythema, dry desquamation, itching, and ulcer)

Timepoint

Just before drug treatment and then weekly for end of radioterapy

Method of measurement

According to RTOG scoring system with a questionnaire

Secondary outcomes

empty

Intervention groups

1

Description

Patients undergoing radiotherapy will receive topical atorvastatin containing BD. Gel topically will be administered on skin of breast.

Category

Treatment - Drugs

2

Description

Patients undergoing radiotherapy will receive placebo topica. Gel topically will be administered on skin of breast. I

Category

Placebo

Recruitment centers

1

Recruitment center

Name of recruitment center

Radiotherapy Center, Imam Hospital

Full name of responsible person

Dr Arash Ghasemi

Street address

Radiotherapy Center, Imam Hospital, Mazandaran University of Medical

City

Sari

Sponsors / Funding sources

1

Sponsor

Name of organization / entity

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

Full name of responsible person

Ahmad Ali Enayati

Street address

Mazandaran University of Medical Sciences, Moalem
Sq

City

Sari

Grant name

Grant code / Reference number

2159

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

Yes

Title of funding source

Vice Chancellor for Research and Technology,
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

Department of Radiopharmacy, Faculty of Pharmacy,
Mazandaran University of Medical Sciences

Full name of responsible person

Dr Seyed Jalal Hosseinimehr

Position

Professor

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