Clinical Trial Protocol
Iranian Registry of Clinical Trials

07 Nov 2026

Radioprotective effects of celecoxib on skin toxicity caused by radiotherapy in patients with breast cancer

Protocol summary

Summary

Skin toxicity is a common side effect induced by ionizing radiation in patients during radiotherapy of breast cancer. Celecoxib (CLX) is a COX II inhibitor that widely is used by human for anti-inflammation. In this study we will investigate the protective effect of CLX on acute radiation dermatitis induced by ionizing radiation in patients with breast cancer. This study is a double blind randomized, placebo-controlled clinical trial. Patients will randomize in two groups of case and placebo. Patients will receive oral capsule of placebo or CLX at dose 200 mg bid during radiotherapy. Severity of skin side effects will be visited and recorded according to RTOG criteria during this study.

General information

Acronym

IRCT registration information

IRCT registration number: **IRCT2014100619423N1**
Registration date: **2015-01-20, 1393/10/30**
Registration timing: **prospective**

Last update:
Update count: **0**

Registration date

2015-01-20, 1393/10/30

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

2015-04-09, 1394/01/20

Expected recruitment end date

2016-07-01, 1395/04/11

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Radioprotective effects of celecoxib on skin toxicity caused by radiotherapy in patients with breast cancer

Public title

The evaluation of celecoxib against skin toxicity caused by radiotherapy in patients with breast cancer

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; sing 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 **70 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

Mazandaran University of Medical Sciences

Street address

Mazandaran University of Medical Sciences, Sari, Iran

City

Sari

Postal code

Approval date

2015-03-04, 1393/12/13

Ethics committee reference number

1276

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 radiotehrapy

Method of measurement

According to RTOG scoring system with a questionnair

Secondary outcomes

empty

Intervention groups

1

Description

Patients undergoing radiotherapy will receive celecoxib capsules containing BD.

Category

Treatment - Drugs

2

Description

Patients undergoing radiotherapy will receive placebo capsules containing lactose,BD.

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, Mazandaranl University of Medical Scenices

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

1276

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

Yes

Title of funding source

Vice Chancellor for Research and Technology, Mazandaranl 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

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

Full name of responsible person

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