

Clinical Trial Protocol

Iranian Registry of Clinical Trials

01 Sep 2026

Comparing toxicity and cosmetic outcome of conventional and hypo fractionated radiotherapy with or without boost in breast cancer patients

Protocol summary

Summary

Purpose: comparing toxicity and cosmetic outcome of conventional and hypo fractionated radiotherapy with or without boost in breast cancer patients. Design: randomized, not blinded, control with conventional radiotherapy, unicentric, phase III clinical trial. Population: early stage breast cancer patients (T1-T2 N0) below 70 years old, who have undergone breast conserving surgery and fill in the informed consent enter the study. Patients who have history of collagen vascular diseases, and also if the radiotherapy field separation is more than 22Cm or ejection fraction is less than 50% or those who get lost in follow up are excluded from the study. Intervention: hypo fractionated radiotherapy with or without boost. Time: from 14/05/2013 to 14/05/2016. Outcome: skin, cardiac, pulmonary toxicity and cosmetic outcome

General information

Acronym

IRCT registration information

IRCT registration number: **IRCT2014102519675N1**

Registration date: **2015-06-14, 1394/03/24**

Registration timing: **registered_while_recruiting**

Last update:

Update count: **0**

Registration date

2015-06-14, 1394/03/24

Registrant information

Name

Sare Hosseini

Name of organization / entity

Mashhad University of Medical Science

Country

Iran (Islamic Republic of)

Phone

+98 51 3842 6936

Email address

hosseinis@mums.ac.ir

Recruitment status

Recruitment complete

Funding source

Mashhad University of Medical Sciences

Expected recruitment start date

2014-06-22, 1393/04/01

Expected recruitment end date

2017-06-22, 1396/04/01

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Comparing toxicity and cosmetic outcome of conventional and hypo fractionated radiotherapy with or without boost in breast cancer patients

Public title

The outcomes of hypo fractionated radiotherapy in breast cancer patients

Purpose

Treatment

Inclusion/Exclusion criteria

Inclusion criteria: patients with early stage breast cancer (T1-T2 N0) below 70 years old who have undergone breast conserving surgery and fill in the informed consent. Exclusion criteria: history of collagen vascular disease; field separation more than 22Cm; ejection fraction less than 50%; lost in follow up.

Age

From **20 years** old to **70 years** old

Gender

Female

Phase

3

Groups that have been masked

No information

Sample size

Target sample size: 100

Randomization (investigator's opinion)

Randomized

Randomization description

Blinding (investigator's opinion)

Not blinded

Blinding description

Placebo

Not used

Assignment

Parallel

Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee

Mashhad University of Medical Sciences

Street address

Between Shahid Javan and Shahid Aleshahidi Sq,
Shahid Fakori Blvd, Mashhad

City

Mashhad

Postal code

9177899191

Approval date

2014-06-14, 1393/03/24

Ethics committee reference number

920067/1/860

Health conditions studied

1

Description of health condition studied

Breast Cancer

ICD-10 code

C50-C50

ICD-10 code description

malignant neoplasm of breast

Primary outcomes

1

Description

Skin toxicity

Timepoint

Every week during intervention then every two weeks in the first month after intervention and then every 3 months up to 2 years

Method of measurement

Based on NCCI Common Toxicity Criteria (CTC) version 20

2

Description

Cardiac toxicity

Timepoint

Before intervention and 4 months after intervention

Method of measurement

Echocardiography

3

Description

Lung toxicity

Timepoint

Before intervention , 6 and 12 months after intervention

Method of measurement

Spirometry

Secondary outcomes

1

Description

Cosmetic outcome

Timepoint

2 years after intervention

Method of measurement

Based on Harvard Criteria

Intervention groups

1

Description

Intervention: hypo fractionated radiotherapy with boost: 42.5 Gy total dose to breast using 2.66 Gy per fraction in 22 days with 6 MV photons with 2 to 2.5 Gy per fraction electron boost in 4 fractions

Category

Treatment - Other

2

Description

Intervention: hypo fractionated radiotherapy without boost: 42.5 Gy total dose to breast using 2.66 Gy per fraction in 22 days with 6 MV photons without electron boost

Category

Treatment - Other

3

Description

Control: standard breast radiotherapy: 50 Gy total dose to breast using 2 Gy per fraction in 35 days with 6 MV photons with 2 to 2.5 Gy per fraction electron boost in 4 fractions

Category

Treatment - Other

Recruitment centers**1****Recruitment center****Name of recruitment center**

Emam Reza hospital

Full name of responsible person

Roham Salek

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2**Recruitment center****Name of recruitment center**

Omid hospital

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3**Recruitment center****Name of recruitment center**

Reza Radiotherapy Center

Full name of responsible person

Fatemeh Varshoei Tabrizi

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Sponsors / Funding sources**1****Sponsor****Name of organization / entity**

Mashhad University of Medical Sciences

Full name of responsible person

Saied Eslami

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Grant name**Grant code / Reference number****Is the source of funding the same sponsor organization/entity?**

Yes

Title of funding source

Mashhad 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**

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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