Clinical Trial Protocol
Iranian Registry of Clinical Trials

23 Oct 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. Iintervention: 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 intervension 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
Street address
Emam Reza Sq, Ebnesina St, Mashhad
City
Mashhad

2

Recruitment center
Name of recruitment center
Omid hospital
Full name of responsible person
Sare Hosseini
Street address
Alandasht Sq, Koohsangi St, Mashhad
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3

Recruitment center
Name of recruitment center
Reza Radiotherapy Center
Full name of responsible person
Fatemeh Varshoee Tabrizi
Street address
19th Misagh, Haft Azar Sq, International Exhibition Blvd
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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
Street address
Ghorshi building, Daneshgah St
City
Mashhad
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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Full name of responsible person
Sare Hosseini
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Assistant Professor
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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