Clinical Trial Protocol
Iranian Registry of Clinical Trials

22 Nov 2026

Acute toxicity and dose constraints of organs at risk in Fast Forward radiotherapy in early stage breast cancer by Tomotherapy and Intensity-Modulated radiation therapy(IMRT)

Protocol summary

Study aim

Acute toxicity and dose constraints of organs at risk in Fast Forward radiotherapy in breast cancer by Tomotherapy and Intensity-Modulated radiation therapy(IMRT) in Omid hospital from 2026 to 2028

Design

Pragmatic Clinical trial with out a control group and single arm with out randomization and with out blinding.

Settings and conduct

Eligible patients in the radiotherapy department of Omid hospital with undergo breast radiotherapy with the IMRT technique using a Tomotherapy machine. The radiotherapy regimen used is based on the Fast Forward protocol and includes a dose of 26 Gy in 5 factions for the whole breast. Additionally for the patients who have an indication for a tumor bed boost, a boost dose of 9Gy in 3 fractions(3 Gy per fraction daily) will be prescribed to the tumor bed.

Participants/Inclusion and exclusion criteria

inclusion criteria: Patients aged 18-70 years with primary breast cancer(T1-T2/N0/M0) treated with breast conserving surgery(who have received adjuvant and neoadjuvant endocrine therapy, chemotherapy, or immunotherapy). exclusion criteria: History of previous radiotherapy to the chest or breast. History of skin or rheumatic diseases. Presence of a chest wall deformity that prevents radiotherapy planning. Use of drugs such as corticosteroids that affect skin response to radiotherapy. Non-completion in fallow up sessions, or withdrawal from the study.

Intervention groups

Eligible patients with undergo breast radiotherapy with the IMRT technique using a Tomotherapy machine based on the Fast Forward protocol and includes a dose of 26 Gy in 5 factions for the whole breast. A boost dose of 9Gy in 3 fractions will be prescribed to the tumor bed.

Main outcome variables

Dose constraints for organ at risk . including the heart, lungs, contralateral breast; radiotherapy complications including firmness and pain, skin erythema, cardiopulmonary complications, and lymphedema

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20261028071588N1**
Registration date: **2026-11-21, 1405/08/30**
Registration timing: **prospective**

Last update: **2026-11-21, 1405/08/30**
Update count: **0**

Registration date

2026-11-21, 1405/08/30

Registrant information

Name

soheila seddighi

Name of organization / entity

Country

Iran (Islamic Republic of)

Phone

+98 51 3853 3388

Email address

soheila482s@gmail.com

Recruitment status

recruiting

Funding source

Expected recruitment start date

2026-11-22, 1405/09/01

Expected recruitment end date

2027-11-22, 1406/09/01

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Acute toxicity and dose constraints of organs at risk in Fast Forward radiotherapy in early stage breast cancer by Tomotherapy and Intensity-Modulated radiation therapy(IMRT)

Public title

Acute toxicity and dose constraints of organs at risk in Fast Forward radiotherapy in breast cancer

Purpose

Treatment

Inclusion/Exclusion criteria

Inclusion criteria:

Patients with primary breast cancer aged 18 to 70 years who are at stage T1-T2/N0/M0 and have undergone breast conserving surgery will be enrolled in the study. Patients who have received systemic therapies including endocrine therapy, chemotherapy, or immunotherapy in the adjuvant or neoadjuvant setting

Exclusion criteria:

Age

From **18 years** old to **70 years** old

Gender

Both

Phase

N/A

Groups that have been masked

No information

Sample size

Target sample size: **37**

Randomization (investigator's opinion)

N/A

Randomization description

Blinding (investigator's opinion)

Not blinded

Blinding description

Placebo

Not used

Assignment

Single

Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee

Ethics committee of Mashhad university of Medical Sciences

Street address

Koohsangi street. Alandasht square. Omid hospital

City

Mashhad

Province

Razavi Khorasan

Postal code

09176613775

Approval date

2026-10-28, 1405/08/06

Ethics committee reference number

IR.MUMS.IRH.REC.1405.167

Health conditions studied

1

Description of health condition studied

breast cancer in early stage(T1-T2/N0/M0) who underwent breast conserving surgery

ICD-10 code

C50

ICD-10 code description

Malignant neoplasm of breast

Primary outcomes

1

Description

Dose constraints for organs at risk including the heart, lungs and contralateral breast; Radiotherapy complications including firmness and pain, skin erythema, pain, cardiopulmonary complications and lymphedema.

Timepoint

Weekly visits during the radiotherapy course until one month; subsequent visits at months 3,6,12 and 18

Method of measurement

Acute and late radiotherapy complications will be assessed using the fallowing standard criteria: for comprehensive evaluation of complications CTCAE(Common Terminology Criteria for Adverse Events) and RTOG(Radiation Therapy Oncology group)/EORTC(European Organization for Research and Treatment of Cancer)for skin complications and radiations reactions. Complication assessment is performed in two ways: Clinician based : by a radiation oncologist during visits. Patient-reported(patient-based):Using validated questionnaires including skin symptoms, pain, edema, and cosmetic satisfaction

Secondary outcomes

1

Description

Evaluation of dose conformity to organ at risk(heart, lungs, contralateral breast

Timepoint

before start of radiotherapy of every patient

Method of measurement

based on Fast forward protocol

2

Description
Evaluation of the relationship between the received dose to organs at risk and the incidence of treatment related complications
Timepoint
at the end of 18 months fallow up
Method of measurement
based on Fast forward protocol

Intervention groups

1

Description
Intervention group: Breast cancer in early stage (T1-T2/N0/M0) who underwent breast conserving surgery
Category
Treatment - Other

Recruitment centers

1

Recruitment center
Name of recruitment center
Omid hospital
Full name of responsible person
Soudabeh Shahidsales
Street address
Koohsangi street. Alandasht square. Omid hospital
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Sponsors / Funding sources

1

Sponsor
Name of organization / entity
Mashhad University of Medical Sciences
Full name of responsible person
Mohsen Tafaghodi
Street address
Daneshgah Street. next to Hoveyzeh cinema. Mashhad University of Medical Sciences. Third floor. Vice Chancellor for Research and Technology
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111111
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TafaghodiM@mums.ac.ir
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
Public
Domestic or foreign origin
Domestic
Category of foreign source of funding
empty
Country of origin
Type of organization providing the funding
Academic

Person responsible for general inquiries

Contact
Name of organization / entity
Mashhad University of Medical Sciences
Full name of responsible person
Soheila Seddighi
Position
Resident
Latest degree
Medical doctor
Other areas of specialty/work
Radiotherapy
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Person responsible for scientific inquiries

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Position
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Latest degree
Specialist
Other areas of specialty/work

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Person responsible for updating data

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Position
Resident

Latest degree
Medical doctor

Other areas of specialty/work
Radiotherapy

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Email
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Sharing plan

Deidentified Individual Participant Data Set (IPD)
Yes - There is a plan to make this available

Study Protocol
Yes - There is a plan to make this available

Statistical Analysis Plan
Yes - There is a plan to make this available

Informed Consent Form
Yes - There is a plan to make this available

Clinical Study Report
Yes - There is a plan to make this available

Analytic Code
Yes - There is a plan to make this available

Data Dictionary
Not applicable

Title and more details about the data/document
Information related to the primary outcome and primary and secondary variables and baseline data of study participants can be shared after de-identifying individuals

When the data will become available and for how long
start of the access period 6 months after the publication of the results

To whom data/document is available
Data will be accessible to both researcher working in academic and scientific institutions as well as individuals working in the industry

Under which criteria data/document could be used
Data will be available for scientific use and improving patients conditions.

From where data/document is obtainable
Via Email

What processes are involved for a request to access data/document
Initially the requester sends their request via email, and upon approval of the documents related to the individuals identity and their objectives for use of these data, the data will be made available to them.

Comments