

Clinical Trial Protocol

Iranian Registry of Clinical Trials

12 Jul 2026

Comparison Of Local Control And Complications Of Hypofractionated Radiotherapy With Conventional In Patients With Advanced Breast Cancer

Protocol summary

Study aim

Comparison of acute complications, late complications, and local control of hypofractionated and conventional radiotherapy of the chest/whole breast and regional lymph nodes

Design

Randomized clinical trial, with parallel groups in two groups of one hundred patients: conventional radiotherapy in 25 fraction and hypofractionated radiotherapy in 15 fraction, who will be assigned to one of the two groups in 1:1 blocks for randomization using a random number table (www.random.org).

Settings and conduct

Radiotherapy Oncology Department, Shahid Rajaei Hospital, Babolsar

Participants/Inclusion and exclusion criteria

Inclusion criteria: Age 18-70 years Performance level KPS $\geq$ 70 or ECOG score=0-1) Newly diagnosed breast cancer Confirmed histological diagnosis T3-4 tumor or lymph node involvement Negative surgical margin
Exclusion criteria: Unwillingness of patient Chronic liver, heart, and kidney diseases Previous chronic lung disease including pulmonary fibrosis, COPD grade III, and asthma Previous history of malignancy Previous history of chest radiotherapy Carcinoma in situ without invasive component Metastasis at initial presentation Connective tissue diseases Positive surgical margin Early stage tumor (T1-2N0) in which there is no indication for lymph node radiotherapy (low-risk patient) Pregnancy

Intervention groups

For radiotherapy, all patients in both groups will be placed in the supine position and undergo CT simulation with 5 mm slices using the Breast Board. The breast/chest and axillary and supraclavicular lymph nodes will be contoured according to RTOG criteria. The treatment dose will be 50 Gy for conventional radiotherapy and 43.5 Gy for hypofractionated radiotherapy.

Main outcome variables

Acute and local complications equivalent to hypofractionation and conventional treatment

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20250728066668N1**

Registration date: **2025-08-01, 1404/05/10**

Registration timing: **prospective**

Last update: **2025-08-01, 1404/05/10**

Update count: **0**

Registration date

2025-08-01, 1404/05/10

Registrant information

Name

Najme Radmard

Name of organization / entity

Country

Iran (Islamic Republic of)

Phone

+98 11 3320 7401

Email address

radmardnajme1@gmail.com

Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2025-08-06, 1404/05/15

Expected recruitment end date

2025-10-07, 1404/07/15

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Comparison Of Local Control And Complications Of Hypofractionated Radiotherapy With Conventional In Patients With Advanced Breast Cancer

Public title

Comparison Of Hypofractionated And Conventional Radiotherapy In Advanced Breast Cancer

Purpose

Treatment

Inclusion/Exclusion criteria**Inclusion criteria:**

All Patients With Advanced Breast Cancer And Confirmed Histologic Diagnosis With Negative Surgical Margin

Exclusion criteria:**Age**

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

Gender

Female

Phase

3

Groups that have been masked

No information

Sample size

Target sample size: **200**

Randomization (investigator's opinion)

Randomized

Randomization description

The patients will be enrolled in the study sequentially and based on the order of referral for the start of radiotherapy. Then, patients will be randomly assigned to one of the two study groups using a random number table (by the site <https://www.random.org>) in 1:1 blocks. An attempt will be made to ensure that patients are the same in terms of age, gender, performance level, initial stage, molecular class, and tumor location in the two groups.

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**

Ethics committee of Babol University of Medical Sciences

Street address

Babol University of Medical Sciences, Ganjafrooz St., Babol, Mazandaran, Iran

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Babol

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Postal code

4717647745

Approval date

2025-04-13, 1404/01/24

Ethics committee reference number

IR.MUBABOL.HRI.REC.1404.005

Health conditions studied**1****Description of health condition studied**

Breast Cancer

ICD-10 code

C50

ICD-10 code description

Malignant neoplasm of breast

Primary outcomes**1****Description**

Acute Complication of Hypofraction And Conventional

Timepoint

Patients will be seen weekly during radiotherapy and once a month afterwards for treatment complications

Method of measurement

A checklist designed based on CTCAE v5.0 (radiotherapy-induced dermatitis), RTOG (subcutaneous toxicity) and SOMA/LENT (telangiectasia, hand edema, pain in the radiotherapy area) will be completed to review the complications of interest

Secondary outcomes

empty

Intervention groups**1****Description**

Intervention Group: Patients with advanced breast cancer undergo hypofractionated radiotherapy treatment for three weeks. During treatment, they are monitored weekly for complications based on the aforementioned criteria, and a follow-up visit is made one month after the end of treatment to check for symptoms.

Category

Treatment - Other

2**Description**

Control group: This group of patients underwent

conventional radiotherapy for five weeks according to standard treatment and were monitored weekly during treatment and then one month after treatment for the occurrence of acute symptoms.

Category

Treatment - Other

Recruitment centers

1

Recruitment center

Name of recruitment center

Shahid Rajaee Hospital, Babolsar

Full name of responsible person

Masoumeh Karimi

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Shahid Rjaee Hospital, Shriati St, Babolsar

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Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Babol University of Medical Sciences

Full name of responsible person

Reza Ghadimi

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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

Babol 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

Babol University of Medical Sciences

Full name of responsible person

Najme Radmard

Position

Resident

Latest degree

Medical doctor

Other areas of specialty/work

Radiotherapy

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Person responsible for scientific inquiries

Contact

Name of organization / entity

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Full name of responsible person

Danial Fazilatpanah

Position

Assistant Professor

Latest degree

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Person responsible for updating data

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Full name of responsible person

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Latest degree

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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

Undecided - It is not yet known if there will be 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

Yes - There is a plan to make this available

Title and more details about the data/document

The files are in Excel format and include age, treatment complications, hormone receptors, etc. and can be shared.

When the data will become available and for how long

6 months after results are published

To whom data/document is available

This information is available to researchers working in academic and scientific institutions.

Under which criteria data/document could be used

Any type of analysis on the delivered data is permitted.

From where data/document is obtainable

Please Contact to the Public Accountability Officer Najme Radmard Radmardnajme1@gmail.com

What processes are involved for a request to access data/document

After receiving and viewing the application email and confirming the applicant, the files will be sent within a maximum of one month.

Comments