

Clinical Trial Protocol

Iranian Registry of Clinical Trials

03 Jun 2026

A clinical trial evaluating the results and complications of intraoperative radiotherapy as boost after neoadjuvant chemotherapy in patients with nonmetastatic breast cancer candidate for breast conserving surgery

Protocol summary

Summary

This study will assess results of intraoperative radiotherapy as boost after neoadjuvant chemotherapy in patients with nonmetastatic breast cancer candidate for breast conserving surgery. Recruitment will be done in three treatment centers. Major inclusion criteria comprise of female gender; age between 30 and 70 years; and operable breast cancer patient who is candidate for breast conserving surgery. Major exclusion criterion consist of pregnancy and breast feeding; active collagen vascular diseases; previous history of chest wall radiotherapy; multifocal breast cancer in two separate quadrants of breast; and poor clinical response to the neoadjuvant chemotherapy. The study is unblinded, single-grouped, and prospective. Twenty patients will be incorporated using convenience sampling method and assessed by complete history taking and physical examination, bilateral mammography, and breast/axilla sonography and metastases work-up before the intervention. Then, a detectable marker will be inserted under the guide of sonography in the tumor. Afterwards, the patients will receive neoadjuvant chemotherapy based on the standards of the treating institute. Before each course of chemotherapy, the patients will be examined for clinical response to chemotherapy. At the end of neoadjuvant treatment, the patients will undergo full physical examination and mammographic and sonographic assessment. In case of appropriate clinical response, the patients will undergo lumpectomy two weeks after completion of neoadjuvant treatment. During surgery, the patients will receive 20 gray intraoperative radiotherapy by intrabeam system Zeiss. After surgery, the patients will receive external beam radiotherapy (50 gray to the whole breast and 45 to 50 gray to the supraclavicular lymph node). Patients will be followed up every 3 months during the first 2 year, and then every 6 months until 5 years by physical examination and annual

mammography (or sonography in case of dense breast). Patients will be analyzed based on complications of treatment and two-year disease-free survival.

General information

Acronym

IRCT registration information

IRCT registration number: **IRCT2017091428815N2**

Registration date: **2017-09-28, 1396/07/06**

Registration timing: **registered_while_recruiting**

Last update:

Update count: **0**

Registration date

2017-09-28, 1396/07/06

Registrant information

Name

Seyed Alireza Javadinia

Name of organization / entity

Department of Oncology, Omid Hospital, Mashhad
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Recruitment status

Recruitment complete

Funding source

Vice-chancellery of Research and Technology, Mashhad
University of Medical Sciences

Expected recruitment start date

2017-02-09, 1395/11/21

Expected recruitment end date

2018-12-31, 1397/10/10
Actual recruitment start date
empty
Actual recruitment end date
empty
Trial completion date
empty
Scientific title
A clinical trial evaluating the results and complications of intraoperative radiotherapy as boost after neoadjuvant chemotherapy in patients with nonmetastatic breast cancer candidate for breast conserving surgery
Public title
Results and complications of intraoperative radiotherapy as boost after neoadjuvant chemotherapy
Purpose
Treatment
Inclusion/Exclusion criteria
Inclusion criteria: Women between 30 and 70 years old; informed consent for participation; pathologic confirmation of invasive ductal carcinoma of breast; tumor stages of T3N1M0, T3N0M0, T2N1M0, and T2N0M0 based on classification of American Joint Committee on Cancer; and operable breast cancer patient who is candidate for breast conserving surgery. Exclusion criteria: Pregnancy and breast feeding; active collagen vascular diseases like scleroderma; history of chest wall radiotherapy for Hodgkin lymphoma; multifocal breast cancer in two separate quadrants of breast; presence of metastasis during treatment; and poor clinical response to the neoadjuvant chemotherapy.
Age
From **30 years** old to **70 years** old
Gender
Female
Phase
2
Groups that have been masked
No information
Sample size
Target sample size: **20**
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
Vice-chancellery for Research, Mashhad University of Medical Sciences, Daneshgah Ave.,
City
Mashhad
Postal code
Approval date
2017-02-08, 1395/11/20
Ethics committee reference number
IR.MUMS.fm.REC.1395.545

Health conditions studied

1
Description of health condition studied
Breast cancer
ICD-10 code
C50.9
ICD-10 code description
Breast, unspecified

Primary outcomes

1
Description
two-year disease-free survival
Timepoint
every 3 months
Method of measurement
physical examination and mammography

Secondary outcomes

1
Description
Dermatitis
Timepoint
every 3 months in the first two years; every 6 months in the third to fifth years after intervention
Method of measurement
physical examination

2
Description
Skin necrosis
Timepoint
every 3 months in the first two years; every 6 months in the third to fifth years after intervention
Method of measurement
physical examination

3

Description

Beauty

Timepoint

every 3 months in the first two years; every 6 months in the third to fifth years after intervention

Method of measurement

physical examination

Intervention groups

1

Description

a detectable marker will be inserted under the guide of sonography in the tumor. Afterwards, the patients will receive neoadjuvant chemotherapy based on the standards of the treating institute. Before each course of chemotherapy, the patients will be examined for clinical response to chemotherapy. At the end of neoadjuvant treatment, the patients will undergo full physical examination and mammographic and sonographic assessment. In case of appropriate clinical response, the patients will undergo lumpectomy two weeks after completion of neoadjuvant treatment. During surgery, the patients will receive 20 gray intraoperative radiotherapy by intrabeam system Zeiss. After surgery, the patients will receive external beam radiotherapy (50 gray to the whole breast and 45 to 50 gray to the supraclavicular lymph node). Patients will be followed up every 3 months during the first 2 year, and then every 6 months until 5 years by physical examination and annual mammography (or sonography in case of dense breast).

Category

Treatment - Devices

Recruitment centers

1

Recruitment center

Name of recruitment center

Omid Radiation Oncology Hospital

Full name of responsible person

Dr Fatemeh Homae Shandiz

Street address

Koohsangi Ave.,

City

Mashhad

2

Recruitment center

Name of recruitment center

Radiotherapy Ward of Imam Reza Hospital

Full name of responsible person

Dr Fatemeh Homae Shandiz

Street address

Daneshgah Ave.,

City

Mashhad

3

Recruitment center

Name of recruitment center

Pasteur Hospital

Full name of responsible person

Dr Fatemeh Homae Shandiz

Street address

Pasteur Ave.,

City

Mashhad

Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Vice-chancellery for Research of Mashhad University of Medical Sciences

Full name of responsible person

Dr Mohsen Tafaghodi

Street address

Daneshgah Ave.

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Mashhad

Grant name

Grant code / Reference number

950125

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

Yes

Title of funding source

Vice-chancellery for Research of 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

Omid Hospital

Full name of responsible person

Dr Alireza Keramati

Position

Resident of radiooncology

Other areas of specialty/work

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http://research.mums.ac.ir/webdocument/load.action?webdocument_code=8000&masterCode=8011904

Person responsible for scientific inquiries

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Dr Fatemeh Homaei Shandiz

Position

Radiooncologist

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Person responsible for updating data

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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