Clinical Trial Protocol
Iranian Registry of Clinical Trials

27 Oct 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 University of Medical Sciences

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Iran (Islamic Republic of)

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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 Homaee 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 Homaee Shandiz
Street address
Daneshgah Ave.,
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3

Recruitment center
Name of recruitment center
Pasteur Hospital
Full name of responsible person
Dr Fatemeh Homaee Shandiz
Street address
Pasteur Ave.,
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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.
City
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
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Resident of radiooncology
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Person responsible for scientific inquiries

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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