Clinical Trial Protocol
Iranian Registry of Clinical Trials

08 Nov 2026

Results of intraoperative radiotherapy as a boost in non-metastatic breast cancer undergoing breast conservation surgery

Protocol summary

Study aim
The purpose of the present study was to determine the outcome of intraoperative radiotherapy as an boost dose in non-metastatic breast cancer undergoing breast conserving surgery.

Design
This study is a phase two single group clinical trial without blinding.

Settings and conduct
This multicenter phase II clinical trial study was performed in two radiotherapy centers of Omid Radiology Hospital and Imam Reza Hospital Radiotherapy in 1396-1989.

Participants/Inclusion and exclusion criteria
Patients with clinical stage I and II breast cancer candidates for breast conserving surgery with whole breast radiotherapy were enrolled. Pregnant and lactating patients and patients undergoing neoadjuvant chemotherapy were excluded.

Intervention groups
Patients underwent standard leptectomy with a margin of at least one mm and underwent intraoperative radiation therapy with boost dose of 20 gray with the ZEISS INTRABEAM 50-kV X-ray System. External whole-breast radiotherapy with a dose of 50 gray and, if needed, supraclavicular administration with a total dose of 45-50 gray or hypofractionation to the whole breast was performed with 16 sessions of 2.66 gray was prescribed.

Main outcome variables
Disease-free survival; Skin toxicity; Subcutaneous tissue toxicity toxicity

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20191123045474N1**

Registration date: **2019-11-26, 1398/09/05**

Registration timing: **prospective**

Last update: **2019-11-26, 1398/09/05**

Update count: **0**

Registration date

2019-11-26, 1398/09/05

Registrant information

Name
Elyar Mousa Pour Shahi

Name of organization / entity

Country
Iran (Islamic Republic of)

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+98 51 3842 6936

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mousapourse951@mums.ac.ir

Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2019-12-13, 1398/09/22

Expected recruitment end date

2020-12-12, 1399/09/22

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Results of intraoperative radiotherapy as a boost in non-metastatic breast cancer undergoing breast conservation surgery

Public title

Intraoperative radiotherapy during breast cancer surgery

Purpose
Prevention
Inclusion/Exclusion criteria
Inclusion criteria:
Pathologic diagnosis of invasive ductal breast cancer Breast cancer with size less than or equal to 3 cm No lymph node involvement No distant metastases
Exclusion criteria:
Pregnancy Lactation Active collagen vascular diseases such as scleroderma Previous radiotherapy in diseases such as Hodgkin's lymphoma Multifocal breast cancer Presence of distant metastasis
Age
From **35 years** old to **65 years** old
Gender
Female

Phase
2
Groups that have been masked
No information
Sample size
Target sample size: **50**
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
Daneshgah Ave.
City
Mashhad
Province
Razavi Khorasan
Postal code
9138813944
Approval date
2017-12-13, 1396/09/22
Ethics committee reference number
IR.MUMS.fm.REC.1396.588

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
Disease free survival
Timepoint
Two years after completion of treatment
Method of measurement
Physical examination and breast imaging

2

Description
Overall survival
Timepoint
Two years after completion of treatment
Method of measurement
Follow up of patient

3

Description
Skin toxicity
Timepoint
Two years after completion of treatment
Method of measurement
Physical examination based on toxicity criteria of the Radiation Therapy Oncology Group and the European Organization for Research and Treatment of Cancer

4

Description
Subcutaneous toxicity
Timepoint
Two years after completion of treatment
Method of measurement
Physical examination based on toxicity criteria of the Radiation Therapy Oncology Group and the European Organization for Research and Treatment of Cancer

Secondary outcomes

empty

Intervention groups

1

Description
Intervention group: During breast-conserving surgery, patients will be treated with INTRABEAM 50-kV X-ray source at a dose of 20 Gy. Postoperatively, patients will

receive systemic treatment according to the NCCN 2017 Clinical Guidelines as appropriate, including chemotherapy, hormone therapy, and targeted therapy. whole-breast external beam radiotherapy at a dose of 50 Gy and supraclavicular lymph node at a total dose of 45-50 Gy or hypofractionation to the whole breast at 16 sessions of 2.66 cGy will be subjected to hormone therapy if positive.

Category

Treatment - Devices

Recruitment centers

1

Recruitment center

Name of recruitment center
Omid Hospital
Full name of responsible person
Kazem Anvari
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2

Recruitment center

Name of recruitment center
Imam Reza Hospital
Full name of responsible person
Kazem Anvari
Street address
Emam Reza Hospital Sq.
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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
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RamResearch@mums.ac.ir
Web page address
http://v-research.mums.ac.ir/

Grant name

Grant code / Reference number
960832
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
Elyar Mousa Pour Shahi
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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Associate professor

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Person responsible for updating data

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Medical doctor

Other areas of specialty/work
Radiotherapy

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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
Yes - There is a plan to make this available

Title and more details about the data/document
All potential data is shared after unidentifiable people

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

To whom data/document is available
Researchers working in academic and scientific institutions

Under which criteria data/document could be used
For future research purposes and data comparisons, future studies of data are available.

From where data/document is obtainable
Contact Dr. Anvari, Project Manager, for request any data/document with AnvariK@mums.ac.ir and the address of Mashhad, Koohsangi Ave, Omid Hospital (postcode 9176613775).

What processes are involved for a request to access data/document
After submitting the request to the research team and the project coordinator, the request will be submitted to the Research Committee of the Oncology Radiotherapy Department of Mashhad University of Medical Sciences and decisions will be made on the success or rejection of the request.

Comments