

Clinical Trial Protocol

Iranian Registry of Clinical Trials

01 Sep 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 lepectomy 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)

Phone

+98 51 3842 6936

Email address

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

Street address

Koohsangi Ave.

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Web page address

<http://omid.mums.ac.ir>

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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Web page address

<http://emamreza.mums.ac.ir/>

Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Mashhad University of Medical Sciences

Full name of responsible person

Mohsen Tafaghodi

Street address

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Email

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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Omid hospital, Koohsangi Ave., Shariati Sq.

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Person responsible for scientific inquiries

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Kazem Anvari

Position

Associate professor

Latest degree

Specialist

Other areas of specialty/work

Radiotherapy

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Person responsible for updating data

Contact

Name of organization / entity

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Elyar Mousa Pour Shahi

Position

Resident

Latest degree

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