

Clinical Trial Protocol

Iranian Registry of Clinical Trials

01 Sep 2026

The comparison of transforming growth factor beta-1 serum levels in early-stage breast cancer patients treated with external beam whole breast irradiation plus boost versus interstitial brachytherapy accelerated partial breast irradiation

Protocol summary

Study aim

The comparison of transforming growth factor beta-1 serum levels in early-stage breast cancer patients treated with external beam whole breast irradiation plus boost versus interstitial brachytherapy accelerated partial breast irradiation

Design

This is a randomized clinical trial study with parallel groups, will be conducted on 20 patients with early-stage breast cancer (after breast preservation surgery) candidate for adjuvant radiotherapy. Assignment of patients to the study groups will be done by random-numbers table and using computer.

Settings and conduct

This study will be performed on patients with breast cancer candidate for adjuvant radiotherapy in Golestan hospital, Ahvaz. Twenty patients will be randomly assigned to one of radiation therapy groups. In this study only statistical analyzer will not know about patient grouping.

Participants/Inclusion and exclusion criteria

Inclusion criteria: Age more than 45 years, No invasion to the lymphovascular space, No lymphatic involvement, No distant metastasis; Exclusion criteria: Extensive Intraductal Component, Paget disease of the breast or skin involvement, Synchronous tumor or history of breast cancer, History of malignancy, Pregnancy or lactation.

Intervention groups

In the first group, external irradiation of the whole breast plus boost is performed. The prescribed dose to isocenter will be 42.5 Gray in 16 fractions or 50 Gray in 25 fractions or 50.4 Gray in 28 fractions; In the second group, accelerated partial breast irradiation is performed by multi-catheter interstitial brachytherapy with high dose rate. The recommended dose is 32 Gray in 8 fractions twice a day.

Main outcome variables

Serum level of Transforming Growth Factor Beta-1 (TGFB-1)

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20211212053368N1**

Registration date: **2021-12-20, 1400/09/29**

Registration timing: **prospective**

Last update: **2021-12-20, 1400/09/29**

Update count: **0**

Registration date

2021-12-20, 1400/09/29

Registrant information

Name

Marjan Kouhzad Mohammadi

Name of organization / entity

Country

Iran (Islamic Republic of)

Phone

+98 61 3001 3374

Email address

marjankouhzad@gmail.com

Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2021-12-22, 1400/10/01

Expected recruitment end date

2022-05-22, 1401/03/01

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

The comparison of transforming growth factor beta-1 serum levels in early-stage breast cancer patients treated with external beam whole breast irradiation plus boost versus interstitial brachytherapy accelerated partial breast irradiation

Public title

TGFB-1 level in breast cancer patients treated with external beam whole breast irradiation versus accelerated partial breast irradiation

Purpose

Treatment

Inclusion/Exclusion criteria**Inclusion criteria:**

Age more than 45 years Unifocal and unicentric breast cancer less than or equal to 3 cm in size (including various histologies of invasive ductal, Papillary, mucinous, tubular, edullary and lobular carcinoma and low to moderate risk intraductal carcinoma) No invasion to the lymphovascular space No lymphatic involvement in invasive histologies No distant metastasis Consent to participate in the study

Exclusion criteria:

Extensive Intraductal Component (EIC) in breast imaging evaluation Paget disease of the breast or skin involvement Synchronous tumor or history of breast cancer History of malignancy 5 years before enrollment Pregnancy or lactation History of collagen vascular disease, or genetic diseases such as ataxia Telangiectasia that leads to increased radiation sensitivity

AgeFrom **45 years** old**Gender**

Female

Phase

N/A

Groups that have been masked*No information***Sample size**Target sample size: **20****Randomization (investigator's opinion)**

Randomized

Randomization description

Patients will be assigned into two groups by simple randomization method. Allocation of patients to the study groups will be done by random-numbers table and using computer, and on this basis patients will be included in one of the two treatment groups before starting radiotherapy. The implementation of the random allocation sequence occurs without knowledge of which patient will receive which treatment method.

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 Ahvaz Jundishapur University of Medical Sciences

Street address

Ahvaz Jundishapur University of Medical Sciences, Golestan Blvd.

City

Ahvaz

Province

Khouzestan

Postal code

6135733118

Approval date

2021-12-09, 1400/09/18

Ethics committee reference number

IR.AJUMS.HGOLESTAN.REC.1400.140

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

Breast cancer

ICD-10 code

C50.919

ICD-10 code description

Malignant neoplasm of unspecified site of unspecified female breast

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

Serum level of Transforming Growth Factor Beta-1 (TGFB-1)

Timepoint

Before radiotherapy, immediately after the end of radiotherapy and three months after the end of radiotherapy

Method of measurement

Assessment of serum levels of TGF-beta1 by Enzyme-linked immunosorbent assay technique (ELISA)

Secondary outcomes

empty

Intervention groups

1

Description

Intervention group: external irradiation of the whole breast plus boost (photon or electron) is performed. The prescribed dose to isocenter will be 42.5 Gray in 16 fractions or 50 Gray in 25 fractions or 50.4 Gray in 28 fractions.

Category

Treatment - Other

2

Description

Intervention group: accelerated partial breast irradiation is performed by multi-catheter interstitial brachytherapy with high dose rate. The recommended dose is 32 Gray in 8 fractions twice a day with the help of 60 cobalt source.

Category

Treatment - Other

Recruitment centers

1

Recruitment center

Name of recruitment center

Golestan Hospital

Full name of responsible person

Seyed Mohammad Hosseini

Street address

Golestan Hospital, Faevardin Ave., Golestan Blvd.

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Email

Mohammadi_5842@yahoo.com

Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Ahvaz University of Medical Sciences

Full name of responsible person

Mohammad Badavi

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badavim@yahoo.com

Grant name

Grant code / Reference number

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

Yes

Title of funding source

Ahvaz 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

Ahvaz University of Medical Sciences

Full name of responsible person

Marjan Kouhzad Mohammadi

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

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Position

Resident

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Other areas of specialty/work

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Person responsible for updating data

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Sharing plan

Deidentified Individual Participant Data Set (IPD)

Undecided - It is not yet known if there will be a plan to make this available

Study Protocol

Undecided - It is not yet known if there will be a plan to make this available

Statistical Analysis Plan

Undecided - It is not yet known if there will be 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

Undecided - It is not yet known if there will be a plan to make this available

Analytic Code

Undecided - It is not yet known if there will be a plan to make this available

Data Dictionary

Undecided - It is not yet known if there will be a plan to make this available