Clinical Trial Protocol
Iranian Registry of Clinical Trials

23 Oct 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
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Iran (Islamic Republic of)
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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 unicenric 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
Age
From **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
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Golestan Hospital, Faevardin Ave., Golestan Blvd.
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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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Ahvaz Jundishapur University of Medical Sciences, Golestan Blvd.
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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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Resident

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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