Clinical Trial Protocol
Iranian Registry of Clinical Trials

13 Jul 2026

Comparison of short term results of IORT boost and hypofractionated EBRT after BCS with conventional whole breast radiotherapy and external boost in early breast cancers from 2019 to 2020

Protocol summary

Study aim

Prevalence of complications and aesthetic results of whole breast adjuvant radiotherapy after breast conservation surgery in early breast cancer patients with hypofractionated external beam radiotherapy with intraoperative boost and conventional external beam radiotherapy with external boost

Design

In this study, patients will be assigned to either conventional or hypofractionated radiotherapy groups (34 patients each) according to the physician's opinion for adjuvant radiotherapy (non-random)

Settings and conduct

At Rasool Akram and Khatam Al-Anbia Hospitals, patients with early breast cancer after breast conservation surgery will receive conventional external radiation therapy with conventional boost dose or hypofractionated radiation therapy with intraoperative boost dose

Participants/Inclusion and exclusion criteria

Inclusion criteria are pathologically confirmed breast cancer, age greater than 35 years, tumor size less than 5 centimeters, absence of nodal involvement or involvement of lesser than 3 nodes and margins without tumor involvement in postoperative pathology. Exclusion criteria are in-situ carcinoma without invasive component, tumoral adhesion to thoracic wall or inflammatory carcinoma, Karnofsky performance score<70, history of radiotherapy of chest wall, multiple breast masses greater than 5 centimeters apart, history of connective tissue diseases, previous chronic pulmonary disease, distant metastasis, large breast and pregnancy.

Intervention groups

In the conventional group: after breast conservation surgery, whole breast radiotherapy will be delivered externally with total dose of 50 gray plus boost does of 10 gray to tumor bed. In the hypofractionated group, 10 gray of intraoperative radiotherapy will be performed during surgery and then 42.56 gray of whole breast radiotherapy will be delivered externally.

Main outcome variables

Skin complications; cosmetic results

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20180919041070N2**
Registration date: **2019-12-03, 1398/09/12**
Registration timing: **registered_while_recruiting**

Last update: **2019-12-03, 1398/09/12**
Update count: **0**

Registration date

2019-12-03, 1398/09/12

Registrant information

Name

Pedram Fadavi

Name of organization / entity

Country

Iran (Islamic Republic of)

Phone

+98 21 5522 8584

Email address

fadavi.p@iums.ac.ir

Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2019-11-16, 1398/08/25

Expected recruitment end date

2020-11-15, 1399/08/25

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Comparison of short term results of IORT boost and hypofractionated EBRT after BCS with conventional whole breast radiotherapy and external boost in early breast cancers from 2019 to 2020

Public title

Adjuvant radiotherapy method in breast cancer.

Purpose

Treatment

Inclusion/Exclusion criteria

Inclusion criteria:

Definitive diagnosis of breast cancer on pathological examination Age more than 35 year old Tumor size equal and less than 5 centimeter No regional nodal involvement or involvement of equal and less than 3 nodes in post surgical pathological examination Clear surgical margin in post surgical pathological examination

Exclusion criteria:

Presence of in-situ carcinoma without invasive component Tumoral adhesion to muscles of the chest wall Inflammatory carcinoma karnofsky performance status less than 70% Previous history of the chest wall irradiation Multiple tumoral masses with more than 5 centimeter distance A history of connective tissue diseases including lupus disease and scleroderma Previous chronic pulmonary disease including pulmonary fibrosis, grade III chronic obstructive pulmonary disease and asthma Distant metastasis large breast based on planning target volume in radiotherapy more than 2500 mililiter Pregnancy

Age

From **35 years** old to **60 years** old

Gender

Female

Phase

N/A

Groups that have been masked

No information

Sample size

Target sample size: **68**

Randomization (investigator's opinion)

Not randomized

Randomization description

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

Research Ethics Committee of Medical School of Iran University of Medical Sciences

Street address

Iran University of Medical Sciences, Shahid Hemmat Highway

City

Tehran

Province

Tehran

Postal code

14665-354

Approval date

2019-10-20, 1398/07/28

Ethics committee reference number

IR.IUMS.FMD.REC.1398.319

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

Skin complication of radiotherapy

Timepoint

After the third week of radiotherapy and one year after the completion of radiotherapy

Method of measurement

National Cancer Institute Common Terminology Criteria for Adverse Events version 2.0

2

Description

Cosmotic outcome

Timepoint

[ne year after the completion of radiotherapy

Method of measurement

Objective Measurement of Cosmetic Outcomes

Secondary outcomes

empty

Intervention groups

1

Description
Intervention group: In hypofractionated radiotherapy group, during breast conservation surgery, patients will receive intraoperative electron radiation therapy with 10 gray dose. Postoperatively, patients will receive systemic treatment as required by the National Comprehensive Cancer Network Guidelines, including chemotherapy and Target Therapy. Following completion of this treatment, patients will receive whole breast hypofractionated radiotherapy in 16 sessions at a total dose of 42.56 Gy.
Category
Treatment - Other

2

Description
Control group: In conventional radiotherapy group, patients will receive external radiation therapy with total dose of 50 gray that will be followed by 10 gray extra dose to the tumor bed after breast conservation surgery with negative margin as well as chemotherapy and targeted therapy.
Category
Treatment - Other

Recruitment centers

1

Recruitment center
Name of recruitment center
Rasoul Akram Hospital, Nayesh Street, Mansouri Street, Sattarkhan Street
Full name of responsible person
Nahid Nafisi
Street address
Rasoul Akram Hospital, Nayesh Street, Mansouri Street, Sattarkhan Street
City
Tehran
Province
Tehran
Postal code
1445613131
Phone
+98 21 6651 5001
Email
rcrdcc@iums.ac.ir
Web page address
http://rcrdc.iums.ac.ir

2

Recruitment center
Name of recruitment center
Shohaday-e-haftom-e-tir hospital
Full name of responsible person
Pedram Fadavi
Street address
End of Shahid Rajaee Street, Shahr-e-Ray
City
Tehran
Province
Tehran
Postal code
1886718136
Phone
+98 21 5522 8580
Fax
+98 21 5521 7901
Email
web7tir@iums.ac.ir
Web page address
http://new.iums.ac.ir

Sponsors / Funding sources

1

Sponsor
Name of organization / entity
Iran University of Medical Sciences
Full name of responsible person
Dr. Seyed Kazem Malekoti
Street address
Fifth Floor, Central Headquarters, Iran University of Medical Sciences, Hemet Highway Between Chamran and Sheikh Fazlollah
City
Tehran
Province
Tehran
Postal code
1449614535
Phone
+98 21 8670 2503
Fax
+98 21 8862 2703
Email
research@iums.ac.ir
Web page address
Grant name
2859
Grant code / Reference number
Is the source of funding the same sponsor organization/entity?
Yes
Title of funding source
Iran 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
Iran University of Medical Sciences

Full name of responsible person
Pedram Fadavi

Position
Associate professor

Latest degree
Specialist

Other areas of specialty/work
Radiotherapy

Street address
Shohadaie haftome tir hospital, Rajaei street, Ray town

City
Tehran

Province
Tehran

Postal code
۱۸۸۶۷۱۸۱۳۶

Phone
+98 21 5522 8584

Fax

Email
Fadavi.p@iums.ac.ir

Person responsible for scientific inquiries

Contact

Name of organization / entity
Iran University of Medical Sciences

Full name of responsible person
Pedram Fadavi

Position
Associate professor

Latest degree
Specialist

Other areas of specialty/work
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Street address
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Province
Tehran

Postal code
۱۸۸۶۷۱۸۱۳۶

Phone
+98 21 5522 8584

Fax

Email
Fadavi.p@iums.ac.ir

Person responsible for updating data

Contact

Name of organization / entity
Iran University of Medical Sciences

Full name of responsible person
Bahareh Jafarnejadi

Position
Resident

Latest degree
Medical doctor

Other areas of specialty/work
Radiotherapy

Street address
Shohadaie haftome tir hospital, Rajaei street, Ray town

City
Tehran

Province
Tehran

Postal code
۱۸۸۶۷۱۸۱۳۶

Phone
+98 21 5522 8584

Fax

Email
bahareh.jn@gmail.com

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

Data Dictionary
Not applicable

Title and more details about the data/document
After completing data collection, study protocols, statistical analysis maps and clinical study reports by publishing scientific articles and sharing them on virtual social networks such as Twitter and related educational channels, these will be made public. .

When the data will become available and for how long
These will be available after publication

To whom data/document is available
The medical community, researchers and the general public

Under which criteria data/document could be used
The medical community and researchers can request data to compare the results of this study with other studies in the field of breast radiotherapy.

From where data/document is obtainable
Dr Pedram Fadavi (Fadavi.p@iums.ac.ir)

What processes are involved for a request to access data/document
After receiving the data submission request, the request

will be submitted to the Research Committee of the Radiotherapy Department of Iran University of Medical Sciences and, if approved, will be sent to the Research Ethics Committee of the Faculty of Medicine. Upon final confirmation of the request, the information will be sent by email.

Comments