Clinical Trial Protocol
Iranian Registry of Clinical Trials

16 Sep 2026

Comparison of the effectiveness of neoadjuvant with adjuvant radiotherapy in patients with early breast cancer

Protocol summary

Study aim

Comparison of cancer free survival, early & late (after 6 & 12 monthes) complications, surgical complications & cosmetic results in early stage breast cancer patients were treated with neoadjuvant radiotherapy with adjuvant

Design

A randomized, controlled clinical trial with four arm and parallel groups

Settings and conduct

120 early breast cancer patients referred to Shohaday-e-haftom-e-tir & Rasoul- e-akram Hospital are divided into 4 groups using a random number table. Patients in the control group receive 50Gy as adjunct and interventional group, as neoadjuvant and the boost of each arm is given in the form of a 12Gy as IORT or 10Gy in a conventional manner. The intervention group is referred 4 to 6 weeks after the completion of radiotherapy to undergo surgery. Both groups receive chemotherapy and hormone therapy. Then, cancer free survival, and early ,delayed & surgical complications and cosmetic results are compared in 4 arms

Participants/Inclusion and exclusion criteria

Inclusion criteria: Women aged 18 to 75 years with breast cancer with stage T1-T2 / N0 / M0, which have ER + and HER2- Candidate for Radiation Therapy For the first time, they have had cancer Exclusion criteria: Earlier history of radiation therapy

Intervention groups

First group: patients undergoing neoadjuvant radiotherapy and IORT boost and then chemotherapy and hormone therapy Second group: patients undergoing neoadjuvant radiotherapy and conventional boost and then chemotherapy and hormone therapy Third group: Patients undergoing surgery and chemotherapy, then receive radiation therapy with boost during surgery (control group) Fourth group: Patients undergoing surgery and chemotherapy receive radiotherapy and boost dose as conventional (control group)

Main outcome variables

cancer free survival, early complications, late complications, cosmetic outcomes

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20180919041070N1**
Registration date: **2019-04-04, 1398/01/15**
Registration timing: **registered_while_recruiting**

Last update: **2019-04-04, 1398/01/15**
Update count: **0**

Registration date

2019-04-04, 1398/01/15

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

2019-01-21, 1397/11/01

Expected recruitment end date

2020-01-21, 1398/11/01

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Comparison of the effectiveness of neoadjuvant with adjuvant radiotherapy in patients with early breast cancer

Public title

Effect of radiotherapy time in breast cancer

Purpose

Treatment

Inclusion/Exclusion criteria

Inclusion criteria:

Women with breast cancer with stage T1-T2 / N0 / M0, which have ER + and HER2-- Candidate for Radiation Therapy For the first time, they have had cancer age between 18 to 70 years

Exclusion criteria:

Earlier history of radiation therapy

Age

From **18 years** old to **70 years** old

Gender

Female

Phase

3

Groups that have been masked

No information

Sample size

Target sample size: **120**

Randomization (investigator's opinion)

Randomized

Randomization description

Randomization method: Simple randomization Random unit: Individual Randomization Tool: Random Number table

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 Iran University of Medical Sciences

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

Approval date

2018-12-22, 1397/10/01

Ethics committee reference number

IR.IUMS.REC.1397.704

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

cancer free survival

Timepoint

Every 3 months until two years

Method of measurement

absence of recurrence disease based on examination and ultrasound and mammography

2

Description

Acute skin toxicity due to radiation therapy

Timepoint

Weekly evaluation during radiotherapy and then 4 and 12 weeks after radiotherapy

Method of measurement

Based on acute radiation dermatitis common toxicity criteria

3

Description

Late skin toxicity due to radiation therapy

Timepoint

6 months after radiotherapy and then every 3 months until one year

Method of measurement

Using the RTOG/EORTC radiation morbidity scoring scheme

4

Description

cosmetic results

Timepoint

Six months after radiotherapy and then every 6 months

until 2 years

Method of measurement

RTOG (4 point scoring system), LENT-SOMA score and BCCT software

5

Description

Surgical complications including infection, not wound healing & seroma

Timepoint

After two weeks of surgery

Method of measurement

History,inspection location of ulcer and examination, and ultrasound to estimate the amount of seruma

Secondary outcomes

empty

Intervention groups

1

Description

Intervention group: A group that received neoadjuvant radiation therapy (50 Gy in 25 fraction) and boost dose during surgery (12 Gy IORT)، then receive surgery, chemotherapy, and hormone therapy.

Category

Treatment - Other

2

Description

Intervention group: A group that received neoadjuvant radiation therapy (50 Gy in 25 fraction) and conventional boost dose (10 Gy in 5 fraction) , then receive surgery, chemotherapy, and hormone therapy.

Category

Treatment - Other

3

Description

Intervention group: A group that is undergoing surgery and chemotherapy, then receive adjuvant radiation therapy (50 Gy in 25 fraction) and boost dose during surgery (12 Gy IORT); then they receive hormone therapy.

Category

Treatment - Other

4

Description

Control group: A group that is undergoing surgery and chemotherapy, then receive adjuvant radiation therapy (50 Gy in 25 fraction) and conventional boost dose (10 Gy in 5 fraction); then they receive hormone therapy.

Category

Treatment - Other

Recruitment centers

1

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

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2

Recruitment center

Name of recruitment center

Rasoul Akram Hospital, Nayesh Street, Mansouri Street, Sattarkhan Street

Full name of responsible person

Nahid Nafisi

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Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Iran University of Medical Sciences

Full name of responsible person

Dr. Seyed Kazem Malekoti

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Fifth Floor, Central Headquarters, Iran University of Medical Sciences, Hemet Highway Between Chamran

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Web page address

Grant name

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
Assistant Professor

Latest degree
Specialist

Other areas of specialty/work
Radiotherapy

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Person responsible for updating data

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Full name of responsible person
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Resident of Radiotherapy and Oncology

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Sharing plan

Deidentified Individual Participant Data Set (IPD)
Yes - There is 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

Title and more details about the data/document

Individual data of the participants in the study: The total potential data after being unidentifiable is the sharing of individuals

When the data will become available and for how long

Access 1 year after the results are published

To whom data/document is available

For researchers working in academic and scientific institutions

Under which criteria data/document could be used

If he want to do similar studies or meta-analysis and systematic review

From where data/document is obtainable

Applicants can send their request to the following email address to receive the requested data Dr Mohaditha Shahin Shohaday-e-haftom-e-tir hospital, End of Shahid Rajaee Street, Shahr-e-Ray mohadese.shahin@gmail.com

What processes are involved for a request to access data/document

First, applicants send their request and proposal to following e-mail. after study it, data will be sent within 10 days. It should be noted that the applicant should be obliged to send me the result of his study immediately after the completion of the project. mohadese.shahin@gmail.com

Comments