Clinical Trial Protocol
Iranian Registry of Clinical Trials

08 Nov 2026

Comparison of the early skin toxicity and cosmetic outcome of concomitant boost radiotherapy with sequential boost radiotherapy after breast cancer conserving surgery

Protocol summary

Study aim
Assessment of the possibility of shortening the duration of breast cancer radiation therapy without increasing the side effects

Design
This is a phase 2 randomized clinical trial. The patients are randomized into two groups of concomitant boost and sequential boost. 50 patients are needed in each group (confidence interval 95%, power of 90%). Randomization was done with permuted block method.

Settings and conduct
This study was done at radiation oncology ward , cancer institute, Imam Khomeini hospital complex, Tehran university of medical sciences

Participants/Inclusion and exclusion criteria
18-75 years olds women with pathology proven breast cancer who have undergone breast conserving surgery would be included in the study. Those withe previous radiation therapy, previous cancer, previous skin disease, positive margin on surgery, or multi focal disease are excluded from the study.

Intervention groups
Radiotherapy with concomitant boost technique

Main outcome variables
Acute skin side effects and cosmetic outcome after 6 month and 1 year after radiation completion.

General information

Reason for update

Acronym

IRCT registration information
IRCT registration number: **IRCT20220221054089N1**
Registration date: **2022-06-22, 1401/04/01**
Registration timing: **retrospective**

Last update: **2022-06-22, 1401/04/01**
Update count: **0**

Registration date
2022-06-22, 1401/04/01

Registrant information
Name
reyhane bayani
Name of organization / entity
Country
Iran (Islamic Republic of)
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+98 21 6658 1619
Email address
r.bayani@umsha.ac.ir

Recruitment status
Recruitment complete

Funding source

Expected recruitment start date
2018-08-23, 1397/06/01

Expected recruitment end date
2019-12-27, 1398/10/06

Actual recruitment start date
2019-04-21, 1398/02/01

Actual recruitment end date
2020-02-29, 1398/12/10

Trial completion date
2021-02-28, 1399/12/10

Scientific title
Comparison of the early skin toxicity and cosmetic outcome of concomitant boost radiotherapy with sequential boost radiotherapy after breast cancer conserving surgery

Public title
Effect of boost technique on toxicity of breast cancer radiotherapy

Purpose

Treatment

Inclusion/Exclusion criteria

Inclusion criteria:

Women with pathologically proven breast cancer Age 18-75 Undergoing breast conserving surgery Early staged breast cancer (T1-3,N0-1)

Exclusion criteria:

Previous skin disease Previous breast radiation Previous cancer Positive margin on surgery Multifocal disease

Age

From **18 years** old to **75 years** old

Gender

Female

Phase

2

Groups that have been masked

No information

Sample size

Target sample size: **100**

Actual sample size reached: **82**

Randomization (investigator's opinion)

Randomized

Randomization description

Randomization was done with permuted block method. In blocks with different sizes, patients were randomly assigned to two groups of concomitant boost and sequential boost by using random number tables.

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 Tehran University of Medical Sciences

Street address

Imam Khomeini Hospital Complex, Keshavarz Blvd, Tehran, Iran

City

Tehran

Province

Tehran

Postal code

3314114197

Approval date

2019-04-21, 1398/02/01

Ethics committee reference number

IR.TUMS.IKHC.REC.1398.02

Health conditions studied

1

Description of health condition studied

Breast cancer

ICD-10 code

C50

ICD-10 code description

Malignant neoplasms of breast

Primary outcomes

1

Description

Acute skin toxicity of breast radiotherapy

Timepoint

Weekly during radiotherapy

Method of measurement

Physical exam and grading the skin side effects via Common Terminology Criteria for Adverse Events version 4

2

Description

Cosmetic outcome

Timepoint

6 and 12 months after radiotherapy

Method of measurement

Physical exam and scoring according to Harvard criteria

Secondary outcomes

empty

Intervention groups

1

Description

Intervention group: Concomitant boost with 10 Gray in 5 fraction, one session every weekend.

Category

Treatment - Other

2

Description

Control group: Sequential radiation boost, 10 Gray in 5 fraction at the end of radiation program.

Category

Treatment - Other

Recruitment centers

1

Recruitment center

Name of recruitment center

Radiation Oncology ward, Imam Khomeini Hospital

complex

Full name of responsible person
Reyhane Bayani

Street address
Imam Khomeini Hospital Complex, Keshavarz blvd, Tehran, Iran

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Sponsors / Funding sources

1

Sponsor

Name of organization / entity
Tehran University of Medical Sciences

Full name of responsible person
Akbar Fotohi

Street address
Imam Khomeini Hospital Complex, Keshavarz blvd, Tehran, Iran

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Grant name

Grant code / Reference number

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

Title of funding source
Tehran 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
Tehran University of Medical Sciences

Full name of responsible person
Reyhane Bayani

Position
Resident

Latest degree
Medical doctor

Other areas of specialty/work
Radiotherapy

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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
No - There is not a plan to make this available
Statistical Analysis Plan
No - There is not a plan to make this available
Informed Consent Form
No - There is not a plan to make this available
Clinical Study Report
Yes - There is a plan to make this available
Analytic Code
No - There is not a plan to make this available
Data Dictionary
No - There is not a plan to make this available
Title and more details about the data/document
The data of this study could be available upon reasonable request.
When the data will become available and for how long
After the publication of the study 2022
To whom data/document is available
All researchers
Under which criteria data/document could be used
For ever kind of analysis.
From where data/document is obtainable
Emailing to the responding author: bayani.reyhane@yahoo.com
What processes are involved for a request to access data/document
Emailing to the responding author, data could be available only after the university confirmation.
Comments