Clinical Trial Protocol
Iranian Registry of Clinical Trials

13 Jul 2026

Evaluation of early toxicity of daily and weekly concomitant boost in comparison with conventional boost in early stage breast cancer patients treated with hypofractionated Radiotherapy in 2019-2020 at Cancer Institute of Tehran

Protocol summary

Study aim
To evaluate and comparison of acute toxicity skin tozicity of 3 arm

Design
3-arm randomized clincal trial with control group

Settings and conduct
The sampling is done over patients come to radioncology department of Cancer Institute of Emam Khomeini Hospital Complex

Participants/Inclusion and exclusion criteria
Female older than 18, with stage 1 or 2 breast cancer who underwent breast conservative surgery with negative margin and lymph node Excluding: positive LN at axillary dissection Multifocal tumour, Paget's disease, pathological skin involvement, synchronous or previous breast cancer, other malignant disease, pregnant or lactating Previous irradiation to ipsilateral breast or thorax

Intervention groups
In the weekly concomitant boost dose of 9 grey in 3 fraction, 3grey per fraction over thursday is given And in the daily concomitant boost dose of 8 grey in 16 fraction, .05 Grey per fraction is given everyday of RT

Main outcome variables
Skin changes

General information

Reason for update

Acronym

IRCT registration information
IRCT registration number: **IRCT20201106049287N1**
Registration date: **2021-12-14, 1400/09/23**
Registration timing: **retrospective**
Last update: **2021-12-14, 1400/09/23**
Update count: **0**

Registration date
2021-12-14, 1400/09/23

Registrant information

Name
Naeim Nabian

Name of organization / entity

Country
Iran (Islamic Republic of)

Phone
+98 21 7751 3217

Email address
naeim_nabian2@yahoo.com

Recruitment status
Recruitment complete

Funding source

Expected recruitment start date
2019-09-23, 1398/07/01

Expected recruitment end date
2021-03-20, 1399/12/30

Actual recruitment start date
2019-11-30, 1398/09/09

Actual recruitment end date
2021-06-20, 1400/03/30

Trial completion date
2021-07-21, 1400/04/30

Scientific title
Evaluation of early toxicity of daily and weekly concomitant boost in comparison with conventional boost in early stage breast cancer patients treated with hypofractionated Radiotherapy in 2019-2020 at Cancer Institute of Tehran

Public title

Evaluation of early toxicity of daily and weekly concomitant boost in comparison with conventional boost in early stage breast cancer patients treated with hypofractionated Radiotherapy in 2019-2020 at Cancer Institute of Tehran

Purpose

Treatment

Inclusion/Exclusion criteria

Inclusion criteria:

Female Older than 18 Stage 1 or 2 Breast conservating surgery Negative margin Negative lymph node

Exclusion criteria:

positive LN at axillary dissection Multifocal tumour Paget’s disease pathological skin involvement, synchronous or previous breast cancer, other malignant disease, pregnant or lactating patient Previous irradiation to ipsilateral breast or thorax

Age

From **18 years** old

Gender

Female

Phase

3

Groups that have been masked

No information

Sample size

Target sample size: **90**

Actual sample size reached: **92**

Randomization (investigator's opinion)

Randomized

Randomization description

The samples will be determined by random blocking method with 4 blocks and using the table of random numbers by Random Allocation Software. Random assignment to intervention and control groups, description of how to block and allocation sequence for concealment will be done by the person not involved in the research (Allocation Concealment). The allocation ratio of the samples will be (Allocation 1: 1: 1). Patients will be divided into 3 groups receiving Boost radiation therapy weekly, daily and control (Assignment). Then, based on the obtained blocks and in the order of allocation, patients will be treated. This study is Open-Label and will not be blinded.

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 committe of Emam Khomeini Hospital Complex of Tehran University of Medical Science

Street address

Keshavarz Blvd, Dr.Gharib Street

City

Tehran

Province

Tehran

Postal code

۱۴۱۹۷۳۳۱۴۱

Approval date

2019-11-27, 1398/09/06

Ethics committee reference number

IR.TUMS.IKHC.REC.1398.224

Health conditions studied

1

Description of health condition studied

Radiotherpy in Breast Cancer

ICD-10 code

C50

ICD-10 code description

Malignant neoplasm of breast

Primary outcomes

1

Description

Skin Reactin

Timepoint

After Radiotherapy, 1 month later, every 3 months up to 1 year

Method of measurement

Use NCI CTCAE version 3.0 toxicity criteria and rates of acute toxicity

Secondary outcomes

1

Description

cosmetic result

Timepoint

3 months

Method of measurement

Comparison with healthy opposite breasts in size, indentation, shape and symmetry

Intervention groups

1

Description

Intervention group: daily concurrent RT boost. In the concomitant boost group, a total dose of 8 grey will be treated with 50 c-grey daily with basic radiotherapy.

Category

Treatment - Other

2

Description
Intervention group: weekly RT boost. In the weekly concomitant boost group, a total dose of 9 grey in 3 sessions on Thursdays of each week will be treated with a dose of 3 grey in each session.
Category
Treatment - Other

Recruitment centers

1

Recruitment center
Name of recruitment center
Emam Khomeini Hospital Complex
Full name of responsible person
Naeim Nabian
Street address
Keshavar Blvd, Dr.Gharib Street
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Sponsors / Funding sources

1

Sponsor
Name of organization / entity
Tehran University of Medical Sciences
Full name of responsible person
Dr. Mohammad Ali Sahraeian
Street address
Imam khomeini Hospital, Blv Keshavarz
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naeim_nabian2@yahoo.com
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
Naeim Nabian
Position
Resident
Latest degree
Medical doctor
Other areas of specialty/work
Radiotherapy
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Sharing plan

Deidentified Individual Participant Data Set (IPD)
Yes - There is 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
Yes - There is a plan to make this available

Data Dictionary
Not applicable

Title and more details about the data/document
Charctristics of patients based on age, TNM staging, hormone receptor, quality and quantity of toxicities and cosmetic results

When the data will become available and for how long
Between 6 months or 1 year after publication

To whom data/document is available
Just researchers at university or scientific organizations

Under which criteria data/document could be used
Not pre spcified

From where data/document is obtainable
Email the writer Naeim_nabian2@yahoo.com

What processes are involved for a request to access data/document
The applicant must have submitted their identity information or that of the company in question. Also, the analyzes that are to be done on the data must be sent in advance. And after about 1-3 months, the result of the request will be announced.

Comments