

Clinical Trial Protocol

Iranian Registry of Clinical Trials

01 Sep 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 clinical 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 conserving 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 committee 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

Radiotherapy 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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imamhospital@tums.ac.ir

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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Person responsible for scientific 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

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Person responsible for updating data**Contact****Name of organization / entity**

Tehran University of Medical Sciences

Full name of responsible person

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Position

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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

Charcristics 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