

# Clinical Trial Protocol

## Iranian Registry of Clinical Trials

11 Jun 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 with the 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)

###### Phone

+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

**City**

Tehran

**Province**

Tehran

**Postal code**

3314114197

**Phone**

+98 21 6658 1619

**Email**

bayani.reyhane@yahoo.com

## 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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**Email**

bayani.reyhane@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**

Reyhane Bayani

**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**

Reyhane Bayani

**Position**

Resident

**Latest degree**

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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**