

Clinical Trial Protocol

Iranian Registry of Clinical Trials

10 Jun 2026

Investigation of the Effect of Melatonin on Reduction of the Grade Three Radiation Dermatitis in Breast Cancer Patients: A Randomized Controlled Trial

Protocol summary

Study aim

Effect of Melatonin on reduction of the radiation dermatitis grade III in breast cancer patients

Design

Randomized triple-blinded clinical trial with control group, phase 3

Settings and conduct

Randomization process will be performed in block size of 4 by online internet website of randomization "Sealed Envelope Ltd" available from <https://www.sealedenvelope.com>. The patients will be randomly assigned to Placebo or Melatonin groups. Allocation of codes will be blinded. The main researcher will enroll the participants based on the inclusion criteria according to the codes. The patients will take 20 mg tablet of Melatonin or Placebo from first fraction to two weeks after the last radiotherapy fraction every night. Patients will be evaluated by physician weekly and compared for severity of radiodermatitis and the frequency of radiodermatitis grade three.

Participants/Inclusion and exclusion criteria

Inclusion Criteria: Female patients aged over 18 years old of breast cancer (stage I-III) who had lumpectomy or mastectomy and completed chemotherapy at least 4 weeks prior to the study. The patients will undergo the convectional radiotherapy regimen with daily fraction of 2 Gy. Exclusion Criteria: Pregnancy, breast feeding, epilepsy, serious liver dysfunction, untreated mental illnesses, diabetes mellitus type 1 or 2, uncontrolled hypertension, concurrent immunosuppressive treatments, connective tissue disorders, history of thoracic radiotherapy, asthma or severe allergic reactions, allergy to Melatonin, coagulopathy, taking sedatives or anticoagulants

Intervention groups

Two 20-member groups of intervention and placebo will take 20mg of melatonin or placebo tablet every night

from the first night of the first fraction to two weeks after the last fraction of radiotherapy regimen.

Main outcome variables

Radiation dermatitis grade Based on the standard grading criteria of CTCAE version 4.03)

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20231218060453N1**

Registration date: **2023-12-31, 1402/10/10**

Registration timing: **prospective**

Last update: **2023-12-31, 1402/10/10**

Update count: **0**

Registration date

2023-12-31, 1402/10/10

Registrant information

Name

Fatemeh Pakniyat

Name of organization / entity

Country

Iran (Islamic Republic of)

Phone

+98 21 2712 2540

Email address

fpakniat84@gmail.com

Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2024-01-10, 1402/10/20

Expected recruitment end date

2024-02-20, 1402/12/01

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Investigation of the Effect of Melatonin on Reduction of the Grade Three Radiation Dermatitis in Breast Cancer Patients: A Randomized Controlled Trial

Public title

Melatonin and Reduction of the Radiation Dermatitis in Breast Cancer Patients

Purpose

Supportive

Inclusion/Exclusion criteria**Inclusion criteria:**

Women aged above 18 years old with breast cancer diagnosis (stage I-III) Previous surgery (lumpectomy or mastectomy) Completion of chemotherapy 4 weeks prior to study entry (if it was prescribed for the patient) Radiotherapy regimen with fractionation daily dose of 2 Gy

Exclusion criteria:

Pregnancy Breast-feeding Serious functional disorders of the liver Epilepsy Diabetes mellitus type 1 or 2 Uncontrolled hypertension Concurrent connective tissue disorders History of chest radiation radiotherapy History of asthma or severe allergic reactions Blood coagulation disorders Concurrent immunosuppressive treatments Taking sedative or anticoagulant drugs at the same time Sensitivity to melatonin

Age

From **18 years** old

Gender

Female

Phase

3

Groups that have been masked

- Participant
- Care provider
- Investigator
- Outcome assessor
- Data analyser
- Data and Safety Monitoring Board

Sample size

Target sample size: **40**

Randomization (investigator's opinion)

Randomized

Randomization description

Randomization process will be performed in block sizes of 4 to balance the number of allocated samples. This process will be done by online internet website of randomization (Sealed Envelope Ltd) available from <https://www.sealedenvelope.com> and the patients will be randomly assigned to the control (placebo) or intervention (Melatonin) groups with a one-to-one correspondence. Allocation of codes will be blinded. Patients will be enrolled in the study according to the

codes.

Blinding (investigator's opinion)

Triple blinded

Blinding description

Numbers of randomization process will be placed in the opaque, sealed envelopes with the randomized numbers printed on them. The envelopes will be kept by the blind staff. Allocation of codes will be related to the Melatonin or Placebo and saved in the confidential folder. People involved in the trial including participants(patients), principal investigators, healthcare providers (Physicians, nurses, secretaries etc.), family of patients who care for patients during the trial, data collectors, and outcome assessors and data safety and monitoring board do not know if the recipient is receiving the actual drug or placebo and all of them are blinded. Melatonin tablets 20 mg from Jalinous Pharmaceutical company in both intervention and placebo groups are completely similar in terms of color, shape, smell, size and method of administration. Drugs will be delivered to patient as A or B in the same shape, and nobody knows which of them is true drug and which of them is placebo.

Placebo

Used

Assignment

Parallel

Other design features**Secondary Ids**

empty

Ethics committees**1****Ethics committee****Name of ethics committee**

Ethics Committee of Shahid Beheshti University

Street address

Shahid Beheshti University, Shahid Shahriari Square, Evin, Tehran, Iran

City

Tehran

Province

Tehran

Postal code

1983969411

Approval date

2021-05-08, 1400/02/18

Ethics committee reference number

IR.SBU.REC.1400.128

Health conditions studied**1****Description of health condition studied**

Radiation Dermatitis

ICD-10 code

L58.0

ICD-10 code description

Acute radiodermatitis

+98 21 2271 8000

Email

pr-shohada@sbmu.ac.ir

Primary outcomes

1

Description

Radiation dermatitis grade III

Timepoint

Determination of the grade of radiation dermatitis through direct inspection by physician from the beginning of the study to two weeks after the last radiotherapy fraction weekly

Method of measurement

Based on the standard grading criteria of CTCAE (Common Toxicity Criteria for Adverse Events, version 4.03) for cancer clinical trials

Secondary outcomes

empty

Intervention groups

1

Description

Intervention group: Breast cancer patients (stage I-III) undergoing radiotherapy who take 20 milligram tablet of melatonin every night from first fraction to two weeks after last radiotherapy fraction.

Category

Treatment - Drugs

2

Description

Control group: Breast cancer patients (stage I-III) undergoing radiotherapy regimen take one tablet of placebo every night from first fraction to two weeks after last radiotherapy fraction.

Category

Placebo

Recruitment centers

1

Recruitment center

Name of recruitment center

Radiotherapy Ward of Shohadaye Tajrish Hospital

Full name of responsible person

Dr. Mona Malekzadeh

Street address

Shahrdari Street, Tajrish Square

City

Tehran

Province

Tehran

Postal code

1989934148

Phone

Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Shahid Beheshti University

Full name of responsible person

Seyedeh Mehri Hamidi

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Shahid Beheshti University, Shahid Shahriari Square, Evin, Tehran

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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

Shahid Beheshti University

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

Shahid Beheshti University of Medical Sciences

Full name of responsible person

Shadi Shafaghi

Position

Assistant Professor

Latest degree

Ph.D.

Other areas of specialty/work

Cardiology

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Person responsible for updating data

Contact

Name of organization / entity
Shiraz University of Medical Sciences
Full name of responsible person
Rojan Shokoohizadeh
Position
General Practitioner
Latest degree
Medical doctor
Other areas of specialty/work

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Tehran
Postal code
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Email
rozhanshokouhi@gmail.com

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

Yes - There is a plan to make this available

Title and more details about the data/document

Some images of skin regions with radiodermatitis will be published without revealing patients identity.

When the data will become available and for how long

After publishing results

To whom data/document is available

Allowed for the public

Under which criteria data/document could be used

Extracting the data of this study data for further investigations in this regard is allowed with citing.

From where data/document is obtainable

Studying an article after publication or communicating with the corresponding author via email address of fpakniat84@gmail.com

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

Communicating with the corresponding author via email address of fpakniat84@gmail.com

Comments