Clinical Trial Protocol
Iranian Registry of Clinical Trials

17 Sep 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 andomly 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

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Iran (Islamic Republic of)

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+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, secratories 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

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
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Sponsors / Funding sources

1

Sponsor
Name of organization / entity
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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
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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
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 revealling 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