Clinical Trial Protocol
Iranian Registry of Clinical Trials

29 May 2026

Comparison of the effectiveness of Melatonin with placebo on radiation induced fatigue in breast cancer patients

Protocol summary

Study aim

Comparing the effectiveness of melatonin administration compared to placebo on fatigue in breast cancer patients

Design

Clinical trial with a control group; Triple-blinded, randomized, with parallel group, phase 3 on 100 patients. Patients were randomly assigned to one of the two groups under study using a table of random numbers 1:1 blocks will be imported.

Settings and conduct

This clinical trial will be conducted in the radiation oncology department of Namazi Hospital affiliated to Shiraz University of Medical Sciences. The method of implementation of the plan will be that patients with breast cancer, if they are eligible to enter the study (based on inclusion and exclusion criteria), after obtaining informed written consent, will be randomly treated with melatonin 20 mg every night or placebo during adjuvant treatment. The patient, the attending physician, as well as the person who evaluates the side effects of the treatment will be blinded to the study group, and only someone outside the research team (pharmacologist who prepares the drugs) will be blinded to which drug group and which placebo group. will receive will be aware.

Participants/Inclusion and exclusion criteria

Entry requirements: newly diagnosed breast cancer patients who are candidates for adjuvant radiotherapy. non-entry: patients who have a history of previous cancer or previous radiotherapy and not functionally suitable or do not have the necessary cooperation.

Intervention groups

Melatonin group: patients take 20mg Melatonin every night concurrent with RT. Placebo group: patients take Placebo every night concurrent with RT.

Main outcome variables

Average fatigue score in melatonin group before intervention; Average fatigue score in placebo group before the intervention; Average fatigue score in melatonin group after the intervention; Average fatigue score in placebo group after the intervention

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20220907055912N1**
Registration date: **2023-02-07, 1401/11/18**
Registration timing: **prospective**

Last update: **2023-02-07, 1401/11/18**
Update count: **0**

Registration date

2023-02-07, 1401/11/18

Registrant information

Name

Sadaf Sadeghi Yazdankhah

Name of organization / entity

Country

Iran (Islamic Republic of)

Phone

+98 21 2240 4696

Email address

ssadeghiy@yahoo.com

Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2023-02-20, 1401/12/01

Expected recruitment end date

2023-05-21, 1402/02/31

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date
empty

Scientific title
Comparison of the effectiveness of Melatonin with placebo on radiation induced fatigue in breast cancer patients

Public title
Effect of Melatonin on radiation induced fatigue

Purpose
Supportive

Inclusion/Exclusion criteria

Inclusion criteria:
Age 18-65 years old Performance status KPS≥70 (ی ECOG score=0-1) Newly diagnosed breast cancer patient Indication of adjuant chemotherapy Indication of adjuant radiotherapy AC-T chemotherapy regimen

Exclusion criteria:
Lack of consent to participate in the study Kidney, Heart and Liver chronic disease History of previous malignant disease History of previous Radiation therapy Metastasis at presentation

Age
From **18 years** old to **65 years** old

Gender
Female

Phase
3

Groups that have been masked

- Participant
- Investigator
- Outcome assessor

Sample size
Target sample size: **100**

Randomization (investigator's opinion)
Randomized

Randomization description
Patients will be randomly assigned to one of the two studied groups using a random number table with 1:1 blocks. It will be tried to ensure that the patients are the same in terms of age, gender, performance level, presence of underlying disease, and level of quality of life and fatigue before the study. Medicine and placebo (which are similar to medicine in terms of shape, appearance, consistency and smell) will be placed in the same container and marked with A and B codes.

Blinding (investigator's opinion)
Triple blinded

Blinding description
The patient, the attending physician, as well as the person who evaluates the side effects of the treatment will be blinded to the study group; and only someone outside the research team (pharmacologist who prepares the drugs) will be aware of which group receive drug and which group receive placebo.

Placebo
Used

Assignment
Parallel

Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee
Ethics committee of Shiraz university of medical sciences

Street address
Apartment c42, Almas shahr tower, Pezeshkan street, Moaliabad street

City
Shiraz

Province
Fars

Postal code
71876-41331

Approval date
2022-02-09, 1400/11/20

Ethics committee reference number
IR.sums.med.rec.1400.604

Health conditions studied

1

Description of health condition studied
Breast cancer

ICD-10 code
C50

ICD-10 code description
Malignant neoplasm of breast

Primary outcomes

1

Description
Fatigue score in MIF questionnaire and stress score in BDI

Timepoint
Before intervention and after intervention

Method of measurement
MIF fatigue measurement questionnaire, BDI-2 questionnare

Secondary outcomes

empty

Intervention groups

1

Description
Intervention group: In this group, patients take two 10 mg melatonin tablets every night during radiation therapy. Melatonin drug is prepared from Jalinous

pharmaceutical company.

Category

Treatment - Drugs

2

Description

Control group: In this group, patients take two placebo pills every night during radiation therapy. The placebo was prepared from Jalinous pharmaceutical company.

Category

Treatment - Drugs

Recruitment centers

1

Recruitment center

Name of recruitment center

Namazi hospital

Full name of responsible person

Ahmad mosalaei

Street address

Namazi square, Zand street, Shiraz

City

Shiraz

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Postal code

71936-13311

Phone

+98 71 3647 4332

Email

namazee_inf@sums.ac.ir

Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Shiraz University of Medical Sciences

Full name of responsible person

Ali eskandari

Street address

Shiraz university of medical sciences central building, Zand street, Shiraz

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Fars

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71348-14336

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vcrdep@sums.ac.ir

Grant name

Grant code / Reference number

Is the source of funding the same sponsor organization/entity?

Yes

Title of funding source

Shiraz University of Medical Sciences

Proportion provided by this source

70

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

Shiraz University of Medical Sciences

Full name of responsible person

Sadaf Sadeghi yazdankhah

Position

Resident

Latest degree

Medical doctor

Other areas of specialty/work

Radiotherapy

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Person responsible for scientific inquiries

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Full name of responsible person

Sadaf Sadeghi yazdankhah

Position

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Person responsible for updating data

Contact
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Sharing plan

Deidentified Individual Participant Data Set (IPD)
No - There is not a plan to make this available
Justification/reason for indecision/not sharing IPD
There is no further information
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
No - There is not 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