Clinical Trial Protocol
Iranian Registry of Clinical Trials

08 Nov 2026

A study on the effects of melatonin supplementation in improving chemotherapy-induced fatigue in breast cancer patients over 50 years old

Protocol summary

Study aim
Determining the effect of melatonin supplementation on improving chemotherapy-induced fatigue in breast cancer patients over 50 years old

Design
Multi-center two-arm phase 3 parallel group randomised trial with blinded postoperative care and outcome assessment planed for 72 patients

Settings and conduct
In oncology clinics, interventionally, double-blind, with explanation, and obtaining informed consent from the patient, alongside standard treatment

Participants/Inclusion and exclusion criteria
Inclusion Criteria: Informed consent to participate in the study. Breast cancer patients over 50 years old who require adjuvant or neoadjuvant chemotherapy. Patients with a functional level of 0 or 1 based on ECOG PS questionnaire. Exclusion Criteria: Patients with known underlying diseases that can exacerbate fatigue Use of sleep aids or fatigue-improving medications before the start of the intervention. Unwillingness to continue participation in the study. Lifestyle that interferes with the nocturnal sleep rhythm. Previous history of chemotherapy. Diagnosis of metastasis. Development of severe toxicities that cannot be controlled with standard doses, such as nausea

Intervention groups
Each patient in the intervention group will receive 5 mg of melatonin daily, starting one week before the initiation of chemotherapy and continuing for one month after its completion, while the control group will receive a placebo.

Main outcome variables
The mean score of chemotherapy-induced fatigue in breast cancer patients over 50 years old in the intervention and control groups before the intervention, after the completion of chemotherapy, and one month after chemotherapy

General information

Reason for update
Acronym
IRCT registration information
IRCT registration number: **IRCT20250314065072N1**
Registration date: **2025-03-23, 1404/01/03**
Registration timing: **prospective**

Last update: **2025-03-23, 1404/01/03**
Update count: **0**

Registration date
2025-03-23, 1404/01/03

Registrant information
Name
shervin mashreghi moghaddam
Name of organization / entity
Country
Iran (Islamic Republic of)
Phone
+98 51 3843 9335
Email address
bdmashreghi@gmail.com

Recruitment status
Recruitment complete
Funding source

Expected recruitment start date
2025-04-05, 1404/01/16
Expected recruitment end date
2026-03-20, 1404/12/29
Actual recruitment start date
empty
Actual recruitment end date
empty

Trial completion date
empty

Scientific title
A study on the effects of melatonin supplementation in improving chemotherapy-induced fatigue in breast cancer patients over 50 years old

Public title
A study on the effects of melatonin supplementation in improving chemotherapy-induced fatigue in breast cancer patients over 50 years old

Purpose
Prevention

Inclusion/Exclusion criteria

Inclusion criteria:
Informed Consent for Study Participation Patients with breast cancer over 50 years old who require adjuvant or neoadjuvant chemotherapy. Patients with a functional level of 0 or 1 based on the Eastern Cooperative Oncology Performance Status (ECOG PS) questionnaire.

Exclusion criteria:
Patients with known underlying conditions including uncontrolled diabetes, uncontrolled high blood pressure, cardiovascular diseases and heart failure, chronic kidney disease, chronic liver disease, autoimmune disease, obstructive respiratory disease, uncontrolled thyroid disorder, history of stroke, seizures, and mental disorder requiring medication. Use of sleep aids or fatigue-reducing medications prior to the start of the intervention. Unwillingness to continue cooperation in the study. Lifestyle that interferes with the nocturnal sleep rhythm (e.g., those who work night shifts). Previous history of chemotherapy. Diagnosis of metastasis. Development of severe toxicities that could not be controlled with standard doses, such as nausea.

Age
From **50 years** old

Gender
Female

Phase
3

Groups that have been masked

- Participant
- Care provider
- Investigator
- Outcome assessor

Sample size
Target sample size: **72**

Randomization (investigator's opinion)
Randomized

Randomization description
A four-block randomization method will be used to assign participants to groups. To allocate 36 samples per group (72 total participants), 18 blocks of 4 are needed. To select the 18 blocks, 18 random numbers between 1 and 6 will be generated with replacement. Thus, a sequence of letters A and B, including 72 letters (36 A's and 36 B's), will be created. Based on the generated sequence, participants will be assigned to groups in order. The random numbers generated in the R software and the random block assigned to the generated numbers. For example, the first person who meets the inclusion criteria for the study will be placed in group B, the second person in group B, the third person in group A, and the fourth person in group A, and so on up to 72 people.

Blinding (investigator's opinion)
Double blinded

Blinding description
Participants, principal investigator, healthcare personnel (doctors, nurses, etc.) responsible for patient care, data collectors, outcome assessors, and those who prepare the manuscript draft.

Placebo
Used

Assignment
Parallel

Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee
Sabzevar University of Medical Sciences

Street address
Vice-Chancellor for Research and Technology, Campus of Sabzevar University of Medical Sciences, after the shohada gomnam Memorial, shohada hasteyi Boulevard.

City
sabzevar

Province
Razavi Khorasan

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9175995957

Approval date
2025-03-08, 1403/12/18

Ethics committee reference number
IR.MEDSAB.REC.1403.182

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 FACIT-Fatigue

Timepoint

evaluation of the fatigue score one week before intervention, after chemotherapy and one month after the end of chemotherapy

Method of measurement

FACIT-Fatigue quastionaire

Secondary outcomes

empty

Intervention groups

1

Description

Intervention group: will receive 5 mg of melatonin produced by Tehran Darou Pharmaceutical Company daily from one week before the start of chemotherapy to one month after the end of it

Category

Treatment - Drugs

2

Description

Control group: will receive placebo daily from one week before the start of chemotherapy to one month after the end of it

Category

Placebo

Recruitment centers

1

Recruitment center

Name of recruitment center

Vasei Hospital

Full name of responsible person

seyed alireza javadinia

Street address

Vasei hospital., Shohaday Hasteyi Blvd., Sabzevar

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2

Recruitment center

Name of recruitment center

Omid hospital

Full name of responsible person

Sareh Hosseini

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3

Recruitment center

Name of recruitment center

Shahid Rajaee Hospital

Full name of responsible person

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4

Recruitment center

Name of recruitment center

Baqiyatallah Hospital

Full name of responsible person

Alireza Keramati

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Sheykh Bahayi st., Molla Sadra St., Vanak Square., Tehran

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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
Sabzevar 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
Mashhad University of Medical Sciences

Full name of responsible person
Shervin Mashreghi moghaddam

Position
Consultant

Latest degree
Specialist

Other areas of specialty/work
Radiotherapy

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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

Yes - There is a plan to make this available

Title and more details about the data/document

All potential data is shareable after de-identifying individuals

When the data will become available and for how long

Access period begins after results are published

To whom data/document is available

Our data will only be accessible to researchers employed in academic and scientific institutions

Under which criteria data/document could be used

To conduct other similar academic and scientific studies

From where data/document is obtainable

Via Shervin Mashreghi Moghaddam's email bdmashreghi@gmail.com

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

The applicant must provide documentation of their academic and university position, the title of the study, and the type of data usage

Comments