Clinical Trial Protocol
Iranian Registry of Clinical Trials

17 Sep 2026

Two-year follow up of a Randomized, Controlled Trial: the Effects of Melatonin on Fatigue Associated with Breast Cancer and Its Adjuvant Treatments

Protocol summary

Study aim

Determining the Effect of Melatonin in Decresing Fatigue associated with Adjuvant Radiation therapy and Chemotherapy in Breast Cancer Patients follow up

Design

Phase 2-3 clinical trial with 64 patients with control group, with parallel groups, triple blinded, with a randomized block design

Settings and conduct

Female patients with breast cancer,stages I to III admitted at Mahdieh Diagnostic and Therapeutic Center and Besat Hospital for adjuvant radiation therapy and chemotherapy during 1398, were selected using simple randomization method and with full explanation of the study and and Written consent. The admitted patients were randomly (randomly blocked) treated with melatonin or placebo (control group). for blinding ,melatonin and the placebo were placed in similar envelopes in a matte package numbered consecutively.Blocking and preparation of envelopes was done by a non-involved person in data sampling and analysis, and thus the health care provider, the data collector, the participant and the person analyzing the data, were not aware of the intervention type received, and Who is located in each group.in this study, the patients have been followed up for 2 years still taking melatonin in the case group and placebo in the control group

Participants/Inclusion and exclusion criteria

Female breast cancer patients with stage I-III(AJCC) who receive adjuvant chemotherapy and radiation therapy.

Intervention groups

Admitted patients will be randomly assigned to melatonin or placebo(control).Oral melatonin 6 mg (in the form of 2 capsules of 3 mg) will be taken every night from 3-7 days before the start of adjuvant treatment for up to 2 years. Following the previous study, patients have been followed up for 2 years, still taking melatonin in the case group and placebo in the control group.

Main outcome variables

Fatigue severity

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20180426039421N3**
Registration date: **2022-07-17, 1401/04/26**
Registration timing: **retrospective**

Last update: **2022-07-17, 1401/04/26**
Update count: **0**

Registration date

2022-07-17, 1401/04/26

Registrant information

Name

Zahra Kesht pour amlashi

Name of organization / entity

Country

Iran (Islamic Republic of)

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Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2020-03-20, 1399/01/01

Expected recruitment end date

2022-03-21, 1401/01/01

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Two-year follow up of a Randomized, Controlled Trial: the Effects of Melatonin on Fatigue Associated with Breast Cancer and Its Adjuvant Treatments

Public title

follow up of Effects of Melatonin on Fatigue Associated associated with radiotherapy and chemotherapy

Purpose

Supportive

Inclusion/Exclusion criteria

Inclusion criteria:

Breast Cancer Stages I, II, III According to Pathological Reports Patients at least 18 Years Old Have Signed a Written Consent Recevieng Adjuvant Chemotherapy and Radiotherapy No Untreated Hypercalcemia No Systolic Blood Pressure Less Than 100 mm Hg No Warfarin Consumption No Methylphenidate Consumption No Sleep Pills During Melatonin Use No TSH>5/5 or <0/5 No Pregnancy or Breastfeeding

Exclusion criteria:

Not signing a written consent

Age

From **18 years** old

Gender

Female

Phase

2-3

Groups that have been masked

- Participant
- Care provider
- Investigator
- Outcome assessor
- Data analyser

Sample size

Target sample size: **64**

Randomization (investigator's opinion)

Randomized

Randomization description

Any number of female breast cancer patients with stages I to III (according to the AJCC system) will be selected using a simple randomization method and randomly entered patients (random block) will be treated with melatonin or placebo (control group). . With the easy sampling method, eligible ones are randomly divided into intervention and control groups. In this study, allocation of people to two groups will be done using permuted block technique. In this method, A represents the person who receives the intervention and B represents the person who is placed in the control group. Considering the quadruple block; We give code 0 to AABB permutation, code 1 to ABAB permutation, code 2 to ABBA, code 3 to BAAB, code 4 to BBAA and code 5 to 9 to BABA. Then, using the table of random numbers, we will randomly choose a starting point and then consider 21 numbers in rows or columns. Considering the order of the numbers in the table, for each number that we come across, we will assign its permutation, for example, if the first three numbers in the table of random numbers are 1, 0, and 5, then the order of receiving treatment by the first 12 people in the two groups, from left to right will be ABABAABBBABA. Therefore, finally, by choosing the appropriate number of numbers from the table, all the samples will be allocated into two groups

Blinding (investigator's opinion)

Triple blinded

Blinding description

Blinding includes: Participants(patients) Clinical care provider(radiotherapy-oncology physicians and chemotherapy nurses) Researcher and evaluator of the outcome and data analyzer: (radiotherapy-oncology physician) In order to hide allocation, medicine and placebo are put in similar envelopes in the opaque package, which have been numbered. Blocking and preparation of envelopes are performed by a non-involved person in data sampling and analysis. Thus, the clinical care provider, the data collector, the participant and the data analyst, are unaware of the type of intervention received and who is located in each group.

Placebo

Used

Assignment

Parallel

Other design features

Following the previous trial, in this study patients were followed up. During 2 years follow-up, patients were still taking melatonin in the case group and placebo in the control group.

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee

Ethics committee of Hamedan University of Medical Sciences

Street address

Hamedan University of Medical Sciences, Shahid Fahmideh Street, Hamedan

City

Hamedan

Province

Hamadan

Postal code

6517838678

Approval date

2022-01-22, 1400/11/02

Ethics committee reference number

IR.UMSHA.REC.1400.813

Health conditions studied

1

Description of health condition studied
Breast Cance; Cancer Related Fatigue; Melatonin
ICD-10 code
C50
ICD-10 code description
Malignant neoplasm of breast

Primary outcomes

1

Description
Fatigue severity in the BFI questionnaire
Timepoint
2 years after last adjuvant treatment session
Method of measurement
Brief Fatigue Inventory(BFI) questionnaire

Secondary outcomes

empty

Intervention groups

1

Description
Intervention group: Oral Melatonin drug 6 mg(2 capsule of 3 mg) will be taken every night from 3 to 7 days before the start of the adjuvant treatment up to 2 years later.
Category
Rehabilitation

2

Description
Control group: The placebo will be taken every night from 3 to 7 days before the start of the adjuvant treatment until 2 years later
Category
Rehabilitation

Recruitment centers

1

Recruitment center
Name of recruitment center
Mahdieh Diagnostic and Treatment Center
Full name of responsible person
Abdolazim Sedighi Pashaki
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Sponsors / Funding sources

1

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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
Hamedan 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
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Position
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Other areas of specialty/work
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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 more information
Study Protocol
Undecided - It is not yet known if there will be a plan to make this available
Statistical Analysis Plan
Undecided - It is not yet known if there will be a plan to make this available
Informed Consent Form
Undecided - It is not yet known if there will be a plan to make this available
Clinical Study Report
Undecided - It is not yet known if there will be 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