Clinical Trial Protocol
Iranian Registry of Clinical Trials

10 Jun 2026

The Effect of Melatonin on Increasing The Health-Related Quality of Life in Female Patients with Non-metastatic Breast Cancer: Three-year Follow up a Clinical Trial

Protocol summary

Study aim
Three-year Follow up of The Effect of Melatonin on Increasing The Health-Related Quality of Life in Female Patients with Non-metastatic Breast Cancer

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

Settings and conduct
Female patients with breast cancer, stage I to III admitted at Mahdieh Diagnostic and Therapeutic Center and Besat Hospital in Hamadan for adjuvant radiation therapy and chemotherapy during 1398, were selected using a simple randomization method and with a full explanation of the study and written consent. The admitted patients were randomly treated with melatonin or a 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 3 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 3 years. Following the previous study, patients have been followed up for 3 years, still taking melatonin in the case group and placebo in the control group.

Main outcome variables
Quality of Life

General information

Reason for update

Acronym

IRCT registration information
IRCT registration number: **IRCT20221205056712N1**
Registration date: **2023-03-15, 1401/12/24**
Registration timing: **registered_while_recruiting**

Last update: **2023-03-15, 1401/12/24**
Update count: **0**

Registration date
2023-03-15, 1401/12/24

Registrant information

Name
Fateme Sheida

Name of organization / entity

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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
2023-03-21, 1402/01/01

Actual recruitment start date
empty

Actual recruitment end date
empty
Trial completion date
empty

Scientific title
The Effect of Melatonin on Increasing The Health-Related Quality of Life in Female Patients with Non-metastatic Breast Cancer: Three-year Follow up a Clinical Trial

Public title
follow up of Effects of Melatonin on Health-Related Quality of Life
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 Receiving Adjuvant Chemotherapy and Radiotherapy
Exclusion criteria:
Not signing a written consent Untreated Hypercalcemia Systolic Blood Pressure Less Than 100 mm Hg Warfarin Consumption Methylphenidate Consumption Consumption of sleep Pills During Melatonin Use TSH>5/5 or <0/5 Pregnancy or Breastfeeding
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, the 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 the AABB permutation, code 1 to the 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) The 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 has 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 3 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 Hamadan University of Medical Sciences
Street address
Hamedan University of Medical Sciences, Shahid Fahmideh Street, Hamedan
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Hamadan
Postal code
6517838678
Approval date
2023-01-21, 1401/11/01
Ethics committee reference number
IR.UMSHA.REC.1401.903

Health conditions studied

1

Description of health condition studied
Breast Cancer; Health Related Quality of Life; Melatonin
ICD-10 code
C50
ICD-10 code description
Malignant neoplasm of breast

Primary outcomes

1

Description
Quality of life
Timepoint
3 years after last adjuvant treatment session
Method of measurement
European Organization for the Research and Treatment of Cancer Quality of Life Questionnaire (EORTC QLQ-C30)

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 3 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 3 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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Mahdieh Diagnostic and Treatment Center, Parastar Ave., Besat Blvd.
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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
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
Hamedan University of Medical Sciences
Full name of responsible person
Fateme Sheida
Position
Medical student (Intern)
Latest degree
A Level or less
Other areas of specialty/work

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Person responsible for updating data

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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