Clinical Trial Protocol
Iranian Registry of Clinical Trials

10 Jun 2026

Evaluation of the Effect of Melatonin Drug in Decreasing Fatigue Caused by Adjuvant Radiotherapy and Chemotherapy in Women with Breast Cancer: A Clinical Trial

Protocol summary

Study aim
Determining the Effect of Melatonin Drug in Decresing Fatigue Caused by Adjuvant Radiation therapy and Chemotherapy in Breast Cancer Patients

Design
Phase 3 clinical trial with 64 patients with control group, community-based and pragmatic, with parallel groups, triple blinded, with a randomized block design

Settings and conduct
Female breast cancer patients with stages I to III who during the second half of 1397 will be referred to Mahdieh Hospital and Besat Hospital for receiving adjuvant radiation therapy and chemotherapy, using a simple randomization method, and with a full explanation of the study and Written consent will be entered into the study. with a randomized block design patients will be treated with melatonin or placebo(control group). For blinding medicine and placebo are put in similar envelopes in the opaque package, which have been numbered. Blocking and preparation of envelopes is 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, are not aware of the intervention type received, and Who is located in each group

Participants/Inclusion and exclusion criteria
Female breast cancer patients with stage I-III(according to the AJCC) who receive adjuvant chemotherapy and radiation therapy; No Consumption of Warfarin, Methylphenidate and Hypnotics during using Melatonin, No Pregnancy or Breastfeeding

Intervention groups
Patients will be randomly treated with melatonin or placebo(control group). Oral Melatonin Drug 6 mg(2 mg capsule 3 mg) from 3 to 7 days before the start of Adjuvant treatment will be consumed every night until the disease progression

Main outcome variables
Type of treatment; Gender; Age; Fatigue severity; The type of adjuvant treatment

General information

Reason for update
Acronym
IRCT registration information
IRCT registration number: **IRCT20180426039421N1**
Registration date: **2018-06-16, 1397/03/26**
Registration timing: **prospective**

Last update: **2018-09-11, 1397/06/20**
Update count: **1**

Registration date
2018-06-16, 1397/03/26

Registrant information
Name
Zahra Kesht pour amlashi
Name of organization / entity
Country
Iran (Islamic Republic of)
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+98 81 3838 1076
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Recruitment status
Recruitment complete
Funding source

Expected recruitment start date
2018-10-07, 1397/07/15
Expected recruitment end date
2019-03-21, 1398/01/01
Actual recruitment start date
empty

Actual recruitment end date
empty
Trial completion date
empty

Scientific title
Evaluation of the Effect of Melatonin Drug in Decreasing Fatigue Caused by Adjuvant Radiotherapy and Chemotherapy in Women with Breast Cancer: A Clinical Trial

Public title
Effect of Melatonin Drug in Decreasing Fatigue Caused by 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:
Expired During Treatment Stop Using Melatonin during Treatment
Age
From **18 years** old
Gender
Female

Phase
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 stage I-III(according to the AJCC system) are selected by simple randomization method and the patients are randomized (randomized block design) to receive melatonin or placebo (control group) .
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 resident) 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

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
2018-04-21, 1397/02/01
Ethics committee reference number
IR.UMSHA.REC.1397.5

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
4 weeks 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) every night from 3 to 7 days before the start of Adjuvant treatmentwill be used until the disease progresses
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 the disease progresses
Category
Placebo

Recruitment centers

1

Recruitment center
Name of recruitment center
Mahdieh Diagnostic and Treatment Center
Full name of responsible person
Abdulazim Sedighi Pashaki
Street address
Mahdieh Diagnostic and Treatment Center, Parastar Ave., Besat Blvd.
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Sponsors / Funding sources

1

Sponsor
Name of organization / entity
Hamedan University of Medical Sciences
Full name of responsible person
Mohammad Haghighi
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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
Persons

Person responsible for general inquiries

Contact
Name of organization / entity
Hamedan University of Medical Sciences
Full name of responsible person
Zahra Kesht Pour Amlashi
Position
Resident
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Person responsible for updating data

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Sharing plan

Deidentified Individual Participant Data Set (IPD)
Undecided - It is not yet known if there will be a plan to make this available
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
Undecided - It is not yet known if there will be a plan to make this available
Data Dictionary
Undecided - It is not yet known if there will be a plan to make this available