Clinical Trial Protocol
Iranian Registry of Clinical Trials

06 Jun 2026

The effect of melatonin supplementation on tumor grading, pathologic findings, serum levels of biomarkers related to inflammation and oxidative stress in patient with breast cancer

Protocol summary

Study aim
The aim of this study is to determine melatonin effect on tumor grading, pathologic findings, serum levels of biomarkers related to inflammation and oxidative stress in patient with breast cancer

Design
Randomized, double-blind, placebo-controlled trial.

Settings and conduct
40 patients with breast cancer referred to Shahid-Beheshti hospital will divided into two groups. 20 patients of control group will receive neoadjuvant chemotherapy plus placebo and 20 patients of intervention group will receive chemotherapy plus melatonin supplementation. At the beginning as well as end of intervention, tumor grade, pathological findings, serum levels of biomarkers related to inflammation and oxidative stresswill be measured.

Participants/Inclusion and exclusion criteria
Inclusion criteria: Having breast cancer and over 25 years of age Exclusion criteria: patients' death, liver and renal failure, inappropriate laboratory blood test

Intervention groups
Control group: patients will receive placebo in addition to standard treatment Intervention group: patients will receive melatonin supplementation in addition to standard treatment

Main outcome variables
Tumor grade and pathological findings

General information

Reason for update

Acronym

IRCT registration information
IRCT registration number: **IRCT20171105037262N5**
Registration date: **2020-10-18, 1399/07/27**
Registration timing: **retrospective**
Last update: **2020-10-18, 1399/07/27**
Update count: **0**

Registration date
2020-10-18, 1399/07/27

Registrant information
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Name of organization / entity
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Recruitment status
Recruitment complete

Funding source

Expected recruitment start date
2020-01-21, 1398/11/01

Expected recruitment end date
2020-09-22, 1399/07/01

Actual recruitment start date
empty

Actual recruitment end date
empty

Trial completion date
empty

Scientific title
The effect of melatonin supplementation on tumor grading, pathologic findings, serum levels of biomarkers related to inflammation and oxidative stress in patient with breast cancer

Public title
Evaluation of melatonin effect on breast cancer

Purpose
Treatment
Inclusion/Exclusion criteria
Inclusion criteria:
Having breast cancer at any stage undergoing neoadjuvant chemotherapy Above 25 years of age
Exclusion criteria:
Having renal and liver failure Abnormal blood test
Age
From **25 years** old
Gender
Female

Phase
3
Groups that have been masked

- Participant
- Investigator

Sample size
Target sample size: **40**
Randomization (investigator's opinion)
Randomized
Randomization description
Randomization is performed by the website (https://stattrek.com/statistics/random-number-generator.aspx). Block randomization with 1:1 allocation ratio is applied to have equal group sizes.
Blinding (investigator's opinion)
Double blinded
Blinding description
All participants and researchers or outcomes evaluators are unaware of allocation of study groups
Placebo
Used
Assignment
Parallel
Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee
Name of ethics committee
Ethics committee of Kashan University of Medical sciences
Street address
Ghotb-e-ravandi Blvd
City
Kashan
Province
Isfehan
Postal code
8715988141
Approval date
2019-12-14, 1398/09/23
Ethics committee reference number
IR.KAUMS.NUHEPM.REC.1398.054

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
Tumor grade
Timepoint
At the beginning and end of intervention
Method of measurement
Microscopic

Secondary outcomes

1

Description
Serum levels of biomarkers related to inflammation and oxidative stress
Timepoint
At the beginning and end of interventio
Method of measurement
ELISA

Intervention groups

1

Description
Intervention group: Receiving chemotherapy and melatonin supplementation. Every night one hour prior to sleep, patients will orally receive two 5mg capsules of melatonin for 24 weeks. Neoadjuvant chemotherapy regimen consist of 4 cycle doxorubicin 60mg/m2 and cyclophosphamide 600mg/m2 every 14_21 days followed by 4 cycle paclitaxel 175mg/m2 every 14-21 days. Four to six week after completion of neoadjuvant chemotherapy the patient will undergo surgery.
Category
Treatment - Drugs

2

Description
Control group: Receiving chemotherapy and placebo. Neoadjuvant chemotherapy regimen consist of 4 cycle doxorubicin 60mg/m2 and cyclophosphamide 600mg/m2 every 14_21 days followed by 4 cycle paclitaxel 175mg/m2 every 14-21 days. Four to six week after

completion of neoadjuvant chemotherapy the patient will undergo surgery. Patients will orally receive two placebo capsules (barij essence, Iran) one hour prior to sleep for 24 weeks

Category
Treatment - Drugs

Recruitment centers

1

Recruitment center
Name of recruitment center
Shahid-Beheshti hospital
Full name of responsible person
Amirhassan Matini
Street address
Ghotb-e-ravandi Blvd
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Sponsors / Funding sources

1

Sponsor
Name of organization / entity
Kashan University of Medical Sciences
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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
Kashan 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
Kashan University of Medical Sciences
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Zatollah Asemi
Position
Associate professor
Latest degree
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Person responsible for updating data

Contact

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Kashan University of Medical Sciences

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Position
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Latest degree
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Other areas of specialty/work
General Practitioner

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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
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