

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 stress will 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

Name

mohammadhossein pourhanifeh

Name of organization / entity

kashan university of medical science

Country

Iran (Islamic Republic of)

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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

Isfahan

Postal code

8715988141

Approval date

2019-12-14, 1398/09/23

Ethics committee reference number**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

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Sponsors / Funding sources**1****Sponsor****Name of organization / entity**

Kashan University of Medical Sciences

Full name of responsible person

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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

Full name of responsible person

Zatollah Asemi

Position

Associate professor

Latest degree

Ph.D.

Other areas of specialty/work

Nutrition

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Person responsible for scientific inquiries**Contact****Name of organization / entity**

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Other areas of specialty/work

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Person responsible for updating data

Contact

Name of organization / entity

Kashan University of Medical Sciences

Full name of responsible person

Mohammad Hossein Pourhanifeh

Position

Student

Latest degree

A Level or less

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