Clinical Trial Protocol
Iranian Registry of Clinical Trials

14 Jun 2026

Effects of melatonin supplementation on clinical status and metabolic profiles in overweight or obese women with fibrocystic breast disease

Protocol summary

Study aim

Objective: The aim of this study is to determine the effects of melatonin supplementation on clinical status and metabolic profiles in overweight or obese women with breast fibrocystic disease.

Design

Study design: Randomized double-blind placebo-controlled trial. Patients will be assigned into two groups to receive melatonin supplements (n=30) or placebo (n=30).

Settings and conduct

Among patients with fibrocystic breast disease referred to Beheshti Clinic affiliated to Kashan University of Medical Sciences, 60 patients will be selected according to inclusion and exclusion criteria. Participants, investigators or the assessors of the outcomes are unaware of the study groups. Supplements and placebos are similar in shape and size. Fasting blood samples will be taken at baseline and 12 weeks after the intervention. intervention period: 12 weeks

Participants/Inclusion and exclusion criteria

Inclusion criteria: Overweight or obese women aged 18-45 years and diagnosed with fibrocystic breast disease. Patients with moderate or severe cyclic mastalgia. Exclusion criteria: Malignant breast diseases, taking medicines for reducing pain (such as danazol, tamoxifen, bromocriptine) over the past three months, menopause women, pregnant or breastfeeding women, psychological diseases, the consumption of any herbal or chemical sedative or hormonal medicines during the study, unwillingness to cooperate.

Intervention groups

Intervention group: 10 mg/day melatonin supplement (Zahravi, Tabriz, Iran), one hour before bedtime for 12 weeks. Control group: Placebo (Barij Essence, Kashan, Iran), one hour before bedtime for 12 weeks.

Main outcome variables

Outcomes: Breast Pain Severity and hs-CRP (primary outcomes) and biomarkers of oxidative stress, parameters of mental health, glucose metabolism indices (secondary outcomes) will be quantified at study baseline and end-of-trial

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20170513033941N59**
Registration date: **2019-05-27, 1398/03/06**
Registration timing: **registered_while_recruiting**

Last update: **2019-06-30, 1398/04/09**
Update count: **1**

Registration date

2019-05-27, 1398/03/06

Registrant information

Name

Mohammadreza Sharif

Name of organization / entity

Country

Iran (Islamic Republic of)

Phone

+98 31 5546 3378

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ostadmohammadi-vr@kaums.ac.ir

Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2019-05-22, 1398/03/01

Expected recruitment end date

2019-06-22, 1398/04/01

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Effects of melatonin supplementation on clinical status and metabolic profiles in overweight or obese women with fibrocystic breast disease

Public title

Effects of melatonin supplementation in the treatment of fibrocystic breast disease

Purpose

Treatment

Inclusion/Exclusion criteria

Inclusion criteria:

Patients aged 18-45 years women diagnosed with fibrocystic breast disease having moderate or severe cyclic mastalgia BMI ≥ 25

Exclusion criteria:

Malignant breast diseases Taking medicines for reducing pain (such as danazol, tamoxifen, bromocriptine) over the past three months Menopause women Pregnant or breastfeeding women Psychological diseases The consumption of any herbal or chemical sedative or hormonal medicines during the study Unwillingness to cooperate

Age

From **18 years** old to **45 years** old

Gender

Female

Phase

3

Groups that have been masked

- Participant
- Investigator
- Outcome assessor

Sample size

Target sample size: **60**

Randomization (investigator's opinion)

Randomized

Randomization description

To decrease potential confounding effects, all participants will have stratified randomization according to BMI (<30 and ≥30 kg/m2) and age (<30 and ≥30 y). Then, participants in each block will be randomly allocated into two treatment groups to take either supplements or placebo. Randomization will be done by the use of computer software.

Blinding (investigator's opinion)

Double blinded

Blinding description

Randomization and allocation will be concealed from the researchers and participants until the final analyses are completed. Another person at the general surgery clinic, who is not involved in the trial and not aware of random sequences, will be assigned the participants to the numbered bottles of capsules. Supplements and placebo are in the same packaging at the Barij Essence pharmaceutical company. Only the code is written on the packages. Patients and researcher will not know the type of drug. After analyzing the data, packet codes will be decoded.

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

Ghotbe Ravandi Boulevard, Kashan

City

Kashan

Province

Isfehan

Postal code

8115187159

Approval date

2019-05-06, 1398/02/16

Ethics committee reference number

IR.KAUMS.MEDNT.REC.1398.018

Health conditions studied

1

Description of health condition studied

breast fibrocystic disease

ICD-10 code

N60

ICD-10 code description

Benign mammary dysplasia

Primary outcomes

1

Description

Breast Pain Severity

Timepoint

At the beginning of the study and after 12 weeks of intervention

Method of measurement

Visual analogue scale 0-10

2

Description

high-sensitivity C-reactive protein (hs-CRP)

Timepoint

At the beginning of the study and after 12 weeks of

intervention

Method of measurement

Elisa kit

Secondary outcomes

1

Description

Malondialdehyde

Timepoint

At the beginning of the study and after 12 weeks of intervention

Method of measurement

Spectrophotometry

2

Description

Glutathione

Timepoint

At the beginning of the study and after 12 weeks of intervention

Method of measurement

Spectrophotometry

3

Description

Total antioxidant capacity

Timepoint

At the beginning of the study and after 12 weeks of intervention

Method of measurement

Spectrophotometry

4

Description

Beck Depression Inventory

Timepoint

At the beginning of the study and after 12 weeks of intervention

Method of measurement

Questionnaire

5

Description

Beck Anxiety Inventory

Timepoint

At the beginning of the study and after 12 weeks of intervention

Method of measurement

Questionnaire

6

Description

Pittsburgh Sleep Quality Index

Timepoint

At the beginning of the study and after 12 weeks of intervention

Method of measurement

Questionnaire

7

Description

Triglycerides

Timepoint

At the beginning of the study and after 12 weeks of intervention

Method of measurement

Enzymatic kit

8

Description

Total cholesterol

Timepoint

At the beginning of the study and after 12 weeks of intervention

Method of measurement

Enzymatic kit

9

Description

HDL

Timepoint

At the beginning of the study and after 12 weeks of intervention

Method of measurement

Enzymatic kit

10

Description

Insulin

Timepoint

At the beginning of the study and after 12 weeks of intervention

Method of measurement

Elisa kit

11

Description

Insulin resistance

Timepoint

At the beginning of the study and after 12 weeks of intervention

Method of measurement

Calculation using HOMA formula

Intervention groups

1

Description

Intervention group: 10 mg/day melatonin supplement (Zahravi, Tabriz, Iran), one hour before bedtime for 12 weeks.

Category

Treatment - Drugs

2

Description
Control group: Placebo (Barij Essence, Kashan, Iran), one hour before bedtime for 12 weeks.
Category
Placebo

Recruitment centers

1

Recruitment center
Name of recruitment center
Beheshti Clinic
Full name of responsible person
Dr. Hossein Sadeghi
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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
Dr. Hossein Sadeghi
Position
Resident of general surgery
Latest degree
Medical doctor
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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