

# 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

##### Email address

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  $\geq 25$   
**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  $\geq 30$  kg/m<sup>2</sup>) and age ( $<30$  and  $\geq 30$  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

Isfahan

##### 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

**Street address**

Ghotbe Ravandi Boulevard, Kashan

**City**

Kashan

**Province**

Isfahan

**Postal code**

8115187159

**Phone**

+98 31 5554 0026

**Fax****Email**

sadeghi.h@gmail.com

## Sponsors / Funding sources

### 1

#### Sponsor

**Name of organization / entity**

Kashan University of Medical Sciences

**Full name of responsible person**

Dr. Hamidreza Banafshe

**Street address**

Ghotbe Ravandi Boulevard, Kashan

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banafshe-h@kaums.ac.ir

**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

**Other areas of specialty/work**

General Surgery

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## Person responsible for scientific inquiries

#### Contact

**Name of organization / entity**

Kashan University of Medical Sciences

**Full name of responsible person**

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**Position**

Resident of general surgery

**Latest degree**

Medical doctor

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## Person responsible for updating data

### Contact

**Name of organization / entity**

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**Full name of responsible person**

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**Position**

Resident of general surgery

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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