Clinical Trial Protocol
Iranian Registry of Clinical Trials

08 Jun 2026

Clinical trial of the effect of melatonin supplementation compared with the placebo on metabolic profiles and gene expression related to insulin and lipid in women with polycystic ovary syndrome

Protocol summary

Study aim

Objective: The aim of this study is to determine the effects of melatonin supplementation on metabolic profiles and gene expression related to insulin and lipid in patients with polycystic ovary syndrome.

Design

Study design: Randomized double-blind placebo-controlled trial. Randomization will be done by the use of computer-generated random numbers. Patients will be assigned into two groups to receive supplements (n=30) or placebo (n=30).

Settings and conduct

Among patients with polycystic ovary syndrome referred to Taleghani outpatient Clinic affiliated to Shahid Beheshti 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. At the beginning and the end of the intervention: 12 weeks.

Participants/Inclusion and exclusion criteria

Inclusion criteria: Patients with polycystic ovary syndrome aged 18 to 40 years. Exclusion criteria: Pregnancy, adrenal hyperplasia, androgen-secreting tumors, hyperprolactinemia, thyroid dysfunction, diabetes and other metabolic disorders at enrollment, inflammatory and malignant diseases, taking melatonin supplements, antioxidant and/or anti-inflammatory supplements within 3 months prior to the enrollment, the night shift workers.

Intervention groups

Intervention group: 10 mg melatonin (Zahravi Pharmaceutical Company,Tabriz, Iran) daily for 12 weeks orally. Control group: Placebo (Barij Essence, Kashan, Iran), daily for 12 weeks orally.

Main outcome variables

Outcomes: Glycemic control (primary outcomes), lipid profiles and gene expression related to insulin and lipid (secondary outcomes) will be quantified at study baseline and end-of-trial.

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT2017090533941N23**
Registration date: **2017-11-14, 1396/08/23**
Registration timing: **retrospective**

Last update: **2019-09-18, 1398/06/27**
Update count: **1**

Registration date

2017-11-14, 1396/08/23

Registrant information

Name

Mohammadreza Sharif

Name of organization / entity

Country

Iran (Islamic Republic of)

Phone

+98 31 5546 3378

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Recruitment status

Recruitment complete

Funding source

Vice chancellor for research, Shahid Beheshti University of Medical Sciences

Expected recruitment start date

2017-10-30, 1396/08/08

Expected recruitment end date
2017-11-13, 1396/08/22
Actual recruitment start date
empty
Actual recruitment end date
empty
Trial completion date
empty

Scientific title
Clinical trial of the effect of melatonin supplementation compared with the placebo on metabolic profiles and gene expression related to insulin and lipid in women with polycystic ovary syndrome

Public title
Effect of melatonin supplementation in treatment of patients with polycystic ovary syndrome
Purpose
Treatment
Inclusion/Exclusion criteria
Inclusion criteria:
Patients with polycystic ovary syndrome aged 18 to 40 years
Exclusion criteria:
Pregnancy Adrenal hyperplasia Androgen-secreting tumors Hyperprolactinemia Thyroid dysfunction Diabetes and other metabolic disorders at enrollment Inflammatory and malignant diseases, Taking melatonin supplements, antioxidant and/or anti-inflammatory supplements within 3 months prior to the enrollment The night shift workers
Age
From **18 years** old to **40 years** old
Gender
Female

Phase
N/A
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, after balanced randomisation, participants will be 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
Participants, investigators or the assessors of the outcomes are unaware of the study groups.
Placebo
Used
Assignment
Parallel

Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee
Name of ethics committee
Ethics committee of Shahid Beheshti University of Medical Sciences
Street address
Shahid Beheshti University of Medical Sciences, Yaman st, Velenjak, Chamran highway
City
Tehran
Province
Tehran
Postal code
1985711151
Approval date
2017-10-29, 1396/08/07
Ethics committee reference number
IR.SBMU.RETECH.REC.1396.507

Health conditions studied

1

Description of health condition studied
Polycystic ovary syndrome
ICD-10 code
E28.2
ICD-10 code description
Polycystic ovarian syndrome

Primary outcomes

1

Description
Insulin
Timepoint
At the beginning of the study and after 12 weeks of intervention
Method of measurement
Elisa kit

2

Description
Insulin resistance
Timepoint
At the beginning of the study and after 12 weeks of intervention
Method of measurement
Calculation using HOMA formula

Secondary outcomes

1

Description
Total cholesterol
Timepoint
At the beginning of the study and after 12 weeks of intervention
Method of measurement
Enzymatic kit

2

Description
HDL
Timepoint
At the beginning of the study and after 12 weeks of intervention
Method of measurement
Enzymatic kit

3

Description
Triglycerides
Timepoint
At the beginning of the study and after 12 weeks of intervention
Method of measurement
Enzymatic kit

4

Description
Expressed levels of PPAR-γ gene
Timepoint
At the beginning of the study and after 12 weeks of intervention
Method of measurement
PCR

5

Description
Expressed levels of GLUT-1 gene
Timepoint
At the beginning of the study and after 12 weeks of intervention
Method of measurement
PCR

6

Description
Expressed levels of LDLR gene
Timepoint
At the beginning of the study and after 12 weeks of intervention
Method of measurement
PCR

7

Description
Beck Depression Inventory
Timepoint
At the beginning of the study and after 12 weeks of intervention
Method of measurement
Questionnaire

8

Description
Beck Anxiety Inventory
Timepoint
At the beginning of the study and after 12 weeks of intervention
Method of measurement
Questionnaire

9

Description
Pittsburgh Sleep Quality Index
Timepoint
At the beginning of the study and after 12 weeks of intervention
Method of measurement
Questionnaire

Intervention groups

1

Description
Intervention group: Melatonin supplements (Zahravi Pharmaceutical Company, Tabriz, Iran), 5 mg, two capsules one hour before bedtime for 12 weeks orally.
Category
Treatment - Drugs

2

Description
Control group: Placebo capsule (Barij Essence, Kashan, Iran), two capsules one hour before bedtime for 12 weeks orally.
Category
Treatment - Drugs

Recruitment centers

1

Recruitment center
Name of recruitment center
Taleghani Clinic
Full name of responsible person
Azadeh Shabani
Street address
Taleghani hospital, Yaman st, Velenjak, Chamran highway
City

Tehran
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Sponsors / Funding sources

1

Sponsor
Name of organization / entity
Vice Chancellor for research of Shahid Beheshti University of Medical Sciences
Full name of responsible person
Afshin Zarghi
Street address
Shahid Beheshti University of Medical Sciences, Yaman st, Velenjak, Chamran highway
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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
Vice Chancellor for research of Shahid Beheshti 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
Ph.D of Nutrition
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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