

Clinical Trial Protocol

Iranian Registry of Clinical Trials

04 Aug 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

Email address

ostadmohammadi-vr@kaums.ac.ir

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
Province
Tehran
Postal code
1985711151
Phone
+98 21 2243 2560
Email
Shabani-a@sums.ac.ir

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
City
Tehran
Province
Tehran
Postal code
1985711151
Phone
+98 21 2303 1111
Fax
Email
Zarghi-a@sums.ac.ir

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
Latest degree
Ph.D.
Other areas of specialty/work
Nutrition
Street address
Ghotbe Ravandi Boulevard, Kashan
City
Kashan
Province
Tehran
Postal code
8115187159
Phone
+98 31 5546 3378
Fax
Email
asemi_r@yahoo.com
Web page address

Person responsible for scientific inquiries

Contact

Name of organization / entity
Kashan University of Medical Sciences
Full name of responsible person
Zatollah Asemi
Position
Ph.D of Nutrition
Latest degree
Ph.D.
Other areas of specialty/work
Nutrition
Street address
Ghotbe Ravandi Boulevard, Kashan
City
Kashan
Province
Tehran
Postal code
8115187159
Phone
+98 31 5546 3378
Fax
Email
asemi_r@yahoo.com
Web page address

Person responsible for updating data

Contact

Name of organization / entity
Kashan University of Medical Sciences
Full name of responsible person
Zatollah Asemi
Position
Ph.D of Nutrition
Latest degree
Ph.D.
Other areas of specialty/work
Nutrition

Street address

Ghotbe Ravandi Boulevard, Kashan

City

Kashan

Province

Isfahan

Postal code

8115187159

Phone

+98 31 5546 3378

Fax**Email**

asemi_r@yahoo.com

Web page address**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