

Clinical Trial Protocol

Iranian Registry of Clinical Trials

23 Feb 2026

Clinical trial of the effect of melatonin supplementation compared with the placebo on hormonal profiles, inflammatory factors, oxidative stress biomarkers and gene expression related to inflammation 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 hormonal profiles, inflammatory factors, oxidative stress biomarkers and gene expression related to inflammation 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 Kosar outpatient Clinic affiliated to Arak 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, breastfeeding, patients with sleeping disorders, adrenal hyperplasia, androgen-secreting tumors, hyperprolactinemia, thyroid dysfunction and/or diabetes.

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: Malondialdehyde (primary outcome) and hormonal profiles, inflammatory factors and gene expression related to inflammation (secondary outcome) will be quantified at study baseline and end-of-trial.

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT2017082733941N9**

Registration date: **2017-09-18, 1396/06/27**

Registration timing: **retrospective**

Last update: **2019-09-16, 1398/06/25**

Update count: **1**

Registration date

2017-09-18, 1396/06/27

Registrant information

Name

Mohammadreza Sharif

Name of organization / entity

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Recruitment status

Recruitment complete

Funding source

Vice chancellor for research, Arak University of Medical Sciences

Expected recruitment start date

2017-08-15, 1396/05/24
Expected recruitment end date
2017-08-30, 1396/06/08
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 hormonal profiles, inflammatory factors, oxidative stress biomarkers and gene expression related to inflammation in women with polycystic ovary syndrome

Public title
Effect of melatonin supplementation in treatment of women with polycystic ovary syndrome

Purpose
Treatment

Inclusion/Exclusion criteria

Inclusion criteria:

Patients with polycystic ovary syndrome aged 18 to 40 years

Exclusion criteria:

Pregnancy Breastfeeding Patients with sleeping disorders
Adrenal hyperplasia Androgen-secreting tumors
Hyperprolactinemia Thyroid dysfunction and/or diabetes

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 Arak University of Medical Sciences

Street address

Sardasht Avenue, Vice chancellor for research, Arak University of Medical Sciences

City

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Province

Markazi

Postal code

3817713314

Approval date

2017-08-14, 1396/05/23

Ethics committee reference number

IR.ARAKMU.REC.1396.89

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

Malondialdehyde

Timepoint

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

Method of measurement

Spectrophotometry

Secondary outcomes

1

Description

Glutathione

Timepoint

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

Method of measurement

Spectrophotometry

2

Description

Total antioxidant capacity

Timepoint

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

Method of measurement

Spectrophotometry

3

Description

Total testosterone

Timepoint

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

Method of measurement

Elisa kit

4

Description

SHBG

Timepoint

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

Method of measurement

Elisa kit

5

Description

Hs-CRP

Timepoint

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

Method of measurement

Elisa kit

6

Description

Nitric oxide

Timepoint

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

Method of measurement

Spectrophotometry

7

Description

Expressed levels of TNF- α gene

Timepoint

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

Method of measurement

PCR

8

Description

Expressed levels of IL-1 gene

Timepoint

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

Method of measurement

PCR

9

Description

Expressed levels of IL-8 gene

Timepoint

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

Method of measurement

PCR

10

Description

Expressed levels of TGFB gene

Timepoint

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

Method of measurement

PCR

11

Description

Expressed levels of VEGF gene

Timepoint

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

Method of measurement

PCR

12

Description

Modified Ferriman Gallwey

Timepoint

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

Method of measurement

Questioner

Intervention groups

1

Description

Intervention group: Melatonin supplements (Zahravi, 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 centers1**Recruitment center****Name of recruitment center**

Kosar Clinic

Full name of responsible person

mehri jamilian

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Sponsors / Funding sources1**Sponsor****Name of organization / entity**Vice chancellor for research, Arak 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 sourceVice chancellor for research, Arak 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

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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