

# 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

##### 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, 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**

Arak

**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- $\alpha$  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 centers**1**Recruitment center****Name of recruitment center**

Kosar Clinic

**Full name of responsible person**

mehri jamilian

**Street address**

Emam Khomeyni Avenue, Arak

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**Province**

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**Email**

jamilian.mehri@gmail.com

**Sponsors / Funding sources**1**Sponsor****Name of organization / entity**Vice chancellor for research, Arak University of  
Medical Sciences**Full name of responsible person**

Ali arash Anoushirvani

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Anoushirvani-aa@aums.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, 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**

Nutrition

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**Web page address****Person responsible for scientific inquiries****Contact****Name of organization / entity**

Kashan University of Medical Sciences

**Full name of responsible person**

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## Person responsible for updating data

### Contact

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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