Clinical Trial Protocol
Iranian Registry of Clinical Trials

20 Nov 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)

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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

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-a 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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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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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
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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