

Clinical Trial Protocol

Iranian Registry of Clinical Trials

30 Jun 2026

Investigating the effect of melatonin supplementation on plasma level of Visfatin and insulin sensitivity on women with polycystic ovarian syndrome

Protocol summary

Study aim

Investigating the effect of melatonin supplementation on plasma level of Visfatin and insulin sensitivity on women with polycystic ovarian syndrome

Design

This is a phase 3 parallel double-blind randomized by random block method clinical trial study, with intervention and placebo groups, and 42 patients with polycystic ovary syndrome to evaluate the effect of melatonin supplementation on serum Visfatin and insulin sensitivity index for 8 weeks.

Settings and conduct

After obtaining a license from the Faculty of Nutrition, Tabriz University of Medical Sciences, patient selection will begin. The statistical population will be women with PCOS who referred to the gynecology clinic of Al-Zahra Hospital in Tabriz. The subject of the study and its importance will be explained to patients and the informed consent form will be provided to those who wish to cooperate. The eligibility form including anthropometric information will be completed, the melatonin intake will be assessed using the Melatonin Multiplicity Questionnaire. Fasting blood samples will be taken to assess levels of visfatin, fasting blood sugar, fasting insulin, and insulin sensitivity index. Patients will be randomly divided into two groups, using a random block table. For 8 weeks, every night Patients in the melatonin group will receive 6mg melatonin (2 tablets) (Nature Made, USA), and in the placebo group, 2 placebos similar to melatonin, made by Tabriz School of Pharmacy. During the intervention, will be asked not to change diet and to report any changes.

Participants/Inclusion and exclusion criteria

Women 18 to 40 years old with polycystic ovary syndrome

Intervention groups

Melatonin intake by the intervention group, Placebo

intake by the control group

Main outcome variables

Visfatin; insulin sensitivity

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20210224050490N1**

Registration date: **2021-05-08, 1400/02/18**

Registration timing: **registered_while_recruiting**

Last update: **2021-05-08, 1400/02/18**

Update count: **0**

Registration date

2021-05-08, 1400/02/18

Registrant information

Name

Fakhrosadat Fayazi

Name of organization / entity

Country

Iran (Islamic Republic of)

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+98 61 3320 3407

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Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2021-04-24, 1400/02/04

Expected recruitment end date

2021-07-22, 1400/04/31

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Investigating the effect of melatonin supplementation on plasma level of Visfatin and insulin sensitivity on women with polycystic ovarian syndrome

Public title

Melatonin in PCOS

Purpose

Treatment

Inclusion/Exclusion criteria**Inclusion criteria:**

Women with PCOS 18-40 years old BMI 20-40 Willingness to cooperate

Exclusion criteria:

Pregnancy Lactation Sleep disturbance Shift work Metabolic disease Taking drugs that cause or affect the symptoms of polycystic ovary syndrome Taking drugs that affect insulin sensitivity Taking antioxidant supplements Following a special diet Losing weight more than 5% of current weight in the last 6 months Cigarettes and alcohol

Age

From **18 years** old to **40 years** old

Gender

Female

Phase

3

Groups that have been masked

- Participant
- Care provider
- Investigator
- Outcome assessor

Sample size

Target sample size: **42**

Randomization (investigator's opinion)

Randomized

Randomization description

For randomized allocation performing, permuted block randomization will be used by biohedral blocks. According to the sample size of 42 subjects, 21 blocks will be generated using the online site (www.sealedenvelope.com). Participants will be entered into the study based on the produced sequence. The drug packets will be allocated to the individual with code on them. Therefore, participants will be unaware of the receiving intervention type, as well as the random sequence which will be hidden and unpredictable.

Blinding (investigator's opinion)

Double blinded

Blinding description

To blind the study, unique codes will be used on the medicine boxes. Melatonin and placebo tablets will be placed into the same appearance boxes by an independent third party. Participants will be entered into the study based on the produced sequence. The drug packets will be allocated to the individual with code on

them. Therefore, the participant and the researcher will be unaware of the type of treatment and the random sequence generated during the study will be unpredictable.

Placebo

Used

Assignment

Parallel

Other design features**Secondary Ids**

empty

Ethics committees**1****Ethics committee****Name of ethics committee**

Ethics committee of Tabriz University of Medical Sciences

Street address

Tabriz University of Medical Sciences, Attar Neyshabouri Av., Golgasht St.

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Tabriz

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East Azarbaijan

Postal code

5166/15731

Approval date

2021-04-17, 1400/01/28

Ethics committee reference number

IR. TBZMED.REC. 1400.038

Health conditions studied**1****Description of health condition studied**

Polycystic ovarian syndrome

ICD-10 code

E28.2

ICD-10 code description

Polycystic ovarian syndrome

Primary outcomes**1****Description**

Visfatin

Timepoint

At the beginning of the study and 8 weeks later

Method of measurement

ELISA kit

2**Description**

Fasting blood sugar

Timepoint

At the beginning of the study and 8 weeks later

Method of measurement

Spectrophotometry

3**Description**

Insulin

Timepoint

At the beginning of the study and 8 weeks later

Method of measurement

ELISA kit

4**Description**

Insulin sensitivity

Timepoint

At the beginning of the study and 8 weeks later

Method of measurement

The quantitative insulin-sensitivity check index formula (QUICKI)

Secondary outcomes

empty

Intervention groups**1****Description**

Intervention group: Intake of 6 mg of melatonin (two tablets of 3 mg supplement of Nature Made, USA) one hour before bedtime, for 8 weeks.

Category

Treatment - Other

2**Description**

Control group: Daily intake of two melatonin placebo (made by Pharmacy Faculty, Tabriz University of Medical Sciences) 1 hour before bed, for 8 weeks.

Category

Treatment - Other

Recruitment centers**1****Recruitment center****Name of recruitment center**

Alzahra hospital

Full name of responsible person

Dr Mohammad Alizadeh

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South Artesh Ave

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Sponsors / Funding sources**1****Sponsor****Name of organization / entity**

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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 source

Tabriz 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**

Tabriz University of Medical Sciences

Full name of responsible person

Fakhrosadat Fayazi

Position

Msc student of clinical nutrition

Latest degree

Bachelor

Other areas of specialty/work

Nutrition

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

Tabriz University of Medical Sciences

Full name of responsible person

Dr Mohammad Alizadeh

Position

Professor

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