

# 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)

##### Phone

+98 61 3320 3407

##### Email address

fayazif@tbzmed.ac.ir

##### 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](http://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.

**City**

Tabriz

**Province**

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

**City**

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**Province**

East Azarbaijan

**Postal code**

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

Tabriz University of Medical Sciences

**Full name of responsible person**

Dr. Samiei

**Street address**

Vice Chancellor for Research No 2 Central Building, Tabriz University of Medical Sciences, Daneshgah Street, Tabriz

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mdalizadeh@tbzmed.ac.ir

**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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Golgasht street, Tabriz university of medical sciences

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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