Clinical Trial Protocol
Iranian Registry of Clinical Trials

21 Jul 2026

Investigating the Effect of melatonin and magnesium co-supplementation on metabolic, hormonal, inflammatory parameters and biomarkers of oxidative stress in women with polycystic ovary syndrome

Protocol summary

Study aim
To determine the effect of melatonin and magnesium co-supplementation on metabolic, hormonal, inflammatory parameters and biomarkers of oxidative stress in women with PCOS

Design
Phase 3 clinical trials with a control group, factorial, double-blind, randomized, 84 patient with PCOS, randomized allocation into 4 groups (melatonin, magnesium, cosupplementation, placebo) with permuted block randomization

Settings and conduct
84 patients referring to Alzahra hospital of Tabriz who meet the criteria, will be randomly allocated into 4 groups. General characterization and the assessment of anthropometric, diet, physical activity, sleep quality grade, hirsutism and biochemistry will be conducted for each patient. After 2 months, the above assessment will be re-evaluated. For blinding, a person who will not be involved in protocol will create the randomization list. Tablet and placebo will be placed into identical containers and will be labeled. Investigators and participants will be blind to random assignments.

Participants/Inclusion and exclusion criteria
Inclusion criteria: Patients with PCOS; Age 18-40 years; BMI≤35; Tendency to participate. Exclusion criteria: Pregnancy; Lactation; Sleeping disorders; The night shift workers; Any disease that affects hormonal parameters; Any drugs that may cause menstrual disorders, hirsutism, acne or affect plasma androgen levels, lipid profile, blood glucose or inflammatory factors; Following the special diet; Weight loss of more than 5% body weight in the last 6 months; Taking melatonin, magnesium, antioxidant and/or anti-inflammatory supplements within 3 months prior to the enrollment; Smoking; Alcohol consumption; Migration

Intervention groups
Melatonin and magnesium, Melatonin, Magnesium, Placebo

Main outcome variables
FBS; Insulin; Insulin resistance; Hormonal parameters; MDA; TAC;TNF-α ; hs-CRP; leptin

General information

Reason for update

Acronym

IRCT registration information
IRCT registration number: **IRCT20191130045556N1**
Registration date: **2020-01-12, 1398/10/22**
Registration timing: **registered_while_recruiting**

Last update: **2020-01-12, 1398/10/22**
Update count: **0**

Registration date
2020-01-12, 1398/10/22

Registrant information

Name
reihaneh Mousavi

Name of organization / entity

Country
Iran (Islamic Republic of)

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Recruitment status
Recruitment complete

Funding source

Expected recruitment start date
2019-12-22, 1398/10/01

Expected recruitment end date
2020-07-22, 1399/05/01

Actual recruitment start date
empty
Actual recruitment end date
empty
Trial completion date
empty

Scientific title
Investigating the Effect of melatonin and magnesium co-supplementation on metabolic, hormonal, inflammatory parameters and biomarkers of oxidative stress in women with polycystic ovary syndrome

Public title
Melatonin and magnesium in polycystic ovary syndrome
Purpose
Treatment
Inclusion/Exclusion criteria
Inclusion criteria:
Patients with polycystic ovary syndrome based on Rotterdam criteria Age 18-40 years BMI≤35 Tendency to participate in the study
Exclusion criteria:
Pregnancy Lactation Sleeping disorders The night shift workers Any disease that affects metabolic parameters in this trial including Cushing's Syndrome, hypoglycemia, type I or II Diabetes, androgen secreting tumors or congenital adrenal hyperplasia, hyperprolactinemia, hyperparathyroidism, Thyroid disorders, hypertension, Anemia, Allergy, Asthma, Cardiovascular, Kidney, Liver or Pulmonary diseases, Cancer Any drugs that may cause side effects such as menstrual disorders, hirsutism or acne or drugs that affect plasma androgen levels, lipid profile, blood glucose or inflammatory factors during the last 3 months (such as oral contraceptives (OCP), Ovulation induction, anti-androgenic, insulin-sensitizer, blood glucose lowering, anti-obesity, antidepressants, anti-coagulants, Thiazides, Corticosteroids, Metformin, Lipid lowering, NSAIDs, Aspirin) Following the special diet Weight loss of more than 5% body weight in the last 6 months Taking melatonin, magnesium, antioxidant and/or anti-inflammatory supplements within 3 months prior to the enrollment Taking melatonin, magnesium, antioxidant and/or anti-inflammatory supplements within 3 months prior to the enrollment Smoking Alcohol consumption Migration Unwillingness to continue cooperation
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: **84**
Randomization (investigator's opinion)
Randomized
Randomization description
For randomized allocation performing, permuted block randomization will be used by quadrilateral blocks. According to the sample size of 84 subjects, 21 blocks will be generated using the online site (www.sealedenvelope.com). Participants will be entered into 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 type of intervention that will receive, as well as the random sequence which will be hidden and unpredictable.
Blinding (investigator's opinion)
Double blinded
Blinding description
For blinding and unawareness of participants and investigator, unique codes will be used on the drug boxes. melatonin, magnesium, and placebo tablets will be placed into identical containers by an independent third party. Participants will be entered into 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 type of intervention that will receive, as well as the random sequence which will be hidden and unpredictable.
Placebo
Used
Assignment
Factorial
Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee
Name of ethics committee
Ethics committee of Ahvaz Jundishapur University of Medical Sciences
Street address
Golestan high way., Ahvaz Jundishapur University of Medical Sciences., Ahvaz., Iran
City
Ahvaz
Province
Khouzestan
Postal code
6135715794
Approval date
2019-11-23, 1398/09/02
Ethics committee reference number
IR.AJUMS.REC.1398.637

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

Serum level of melatonin

Timepoint

At the beginning of the study and 8 weeks later

Method of measurement

ELISA kit

2

Description

Serum level of magnesium

Timepoint

At the beginning of the study and 8 weeks later

Method of measurement

Spectrophotometry

3

Description

Fasting blood sugar

Timepoint

At the beginning of the study and 8 weeks later

Method of measurement

Spectrophotometry

4

Description

Insulin

Timepoint

At the beginning of the study and 8 weeks later

Method of measurement

ELISA kit

5

Description

Insulin resistance

Timepoint

At the beginning of the study and 8 weeks later

Method of measurement

insulin resistance formula (HOMA-IR)

6

Description

Serum triglyceride

Timepoint

At the beginning of the study and 8 weeks later

Method of measurement

Spectrophotometry

7

Description

serum Low Density lipoprotein -Cholesterol (LDL-C)

Timepoint

At the beginning of the study and 8 weeks later

Method of measurement

Spectrophotometry

8

Description

serum high Density lipoprotein -Cholesterol (HDL-C)

Timepoint

At the beginning of the study and 8 weeks later

Method of measurement

Spectrophotometry

9

Description

Serum total cholesterol

Timepoint

At the beginning of the study and 8 weeks later

Method of measurement

Spectrophotometry

10

Description

Total Testosterone

Timepoint

At the beginning of the study and 8 weeks later

Method of measurement

ELISA kit

11

Description

Sex hormone-binding globulin (SHBG)

Timepoint

At the beginning of the study and 8 weeks later

Method of measurement

ELISA kit

12

Description

Free androgen index

Timepoint

At the beginning of the study and 8 weeks later

Method of measurement

formula

13

Description

Total antioxidant capacity (TAC)

Timepoint

At the beginning of the study and 8 weeks later

Method of measurement

Chemical method

14

Description
Serum level of Malondialdehyde (MDA)
Timepoint
At the beginning of the study and 8 weeks later
Method of measurement
Thiobarbituric acid method

15

Description
Serum level of tumor necrosis factor alpha (TNF-α)
Timepoint
At the beginning of the study and 8 weeks later
Method of measurement
ELISA kit

16

Description
Serum level of High sensitivity C- Reaction Protein (hs-CRP)
Timepoint
At the beginning of the study and 8 weeks later
Method of measurement
ELISA kit

17

Description
Serum level of leptin
Timepoint
At the beginning of the study and 8 weeks later
Method of measurement
ELISA kit

18

Description
Sleep quality
Timepoint
At the beginning of the study and 8 weeks later
Method of measurement
The Pittsburgh Sleep Quality Index (PSQI)

19

Description
Grading of hirsutism
Timepoint
At the beginning of the study and 8 weeks later
Method of measurement
Ferriman-Gallwey Questionnaire

Secondary outcomes

1

Description
Body mass index (BMI)
Timepoint
At the beginning of the study and 8 weeks later
Method of measurement
BMI Formula

2

Description
Waist circumference
Timepoint
At the beginning of the study and 8 weeks later
Method of measurement
Tape

Intervention groups

1

Description
Intervention group: Two melatonin tablet 3 mg (Nature Made, USA), Daily+ a magnesium tablet (each tablet containing 250 mg magnesium in the form of magnesium oxide) (Jalinous, Iran), daily, for 8 weeks
Category
Treatment - Other

2

Description
Intervention group: Two melatonin tablet 3 mg (Nature Made, USA), Daily+ a magnesium placebo (Pharmacy Faculty, Tabriz, Iran), daily, for 8 weeks
Category
Treatment - Other

3

Description
Intervention group: a magnesium tablet (each tablet containing 250 mg magnesium in the form of magnesium oxide) (Jalinous, Iran), daily+Two melatonin placebo (Pharmacy Faculty, Tabriz, Iran), daily, for 8 weeks
Category
Treatment - Other

4

Description
Control group: Two melatonin placebo (Pharmacy Faculty, Tabriz, Iran), daily+ a magnesium placebo (Pharmacy Faculty, Tabriz, Iran), daily, for 8 weeks
Category
Placebo

Recruitment centers

1

Recruitment center
Name of recruitment center
Alzahra Hospital
Full name of responsible person
Reihaneh Mousavi
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South Artesh Ave
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5138663134
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Sponsors / Funding sources

1

Sponsor
Name of organization / entity
Ahvaz University of Medical Sciences
Full name of responsible person
Dr.Mohammad.Badavi
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Postal code
6135715794
Phone
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Email
itc@ajums.ac.ir
Grant name
Grant code / Reference number
Is the source of funding the same sponsor organization/entity?
Yes
Title of funding source
Ahvaz University of Medical Sciences
Proportion provided by this source
70
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

2

Sponsor
Name of organization / entity
Tabriz University of Medical Sciences
Full name of responsible person
Dr. Mohammad Samiei
Street address
Vice Chancellor for Research No 2 Central Building, Tabriz University of Medical Sciences, Daneshgah Street, Tabriz
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Grant name
Grant code / Reference number
Is the source of funding the same sponsor organization/entity?
No
Title of funding source
Tabriz University of Medical Science
Proportion provided by this source
30
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
Ahvaz University of Medical Sciences
Full name of responsible person
Reihaneh Mousavi
Position
Ph.D Student
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Person responsible for scientific inquiries

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Person responsible for updating data

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Sharing plan

Deidentified Individual Participant Data Set (IPD)
Yes - There is 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
Title and more details about the data/document
Demographic and primary outcomes data of participants
When the data will become available and for how long
Accessibility to data is possible 6 months after publication
To whom data/document is available
Researchers who are working in academic institutes
Under which criteria data/document could be used
Only observation of documents is allowed; Analysis and use of data is not possible.
From where data/document is obtainable
1. Dr. Majid Karandish, Faculty of Paramedicine, Ahvaz Jundishapur University of Medical Sciences,mkarandish@yahoo.com 2. Reihaneh Mousavi, Faculty of Paramedicine, Ahvaz Jundishapur University of Medical Sciences, Re_mousavi@yahoo.com.
What processes are involved for a request to access data/document
The applicator can send a request to the person responsible for the study by email and within 10 days the document will be sent to the requesting person.
Comments