Clinical Trial Protocol
Iranian Registry of Clinical Trials

11 Jun 2026

The effects of combined zinc and magnesium supplementation on metabolic profiles and gene expression related to insulin and lipid in women with polycystic ovary syndrome

Protocol summary

Study aim

Objective: The aim of this study is to determine the effects of combined magnesium and zinc supplementation on metabolic profiles and gene expression related to insulin and lipid in women with polycystic ovary syndrome

Design

Study design: Randomized double-blind placebo-controlled trial, All participants will have stratified randomization according to BMI (<25 and ≥25 kg/m2) and age (<30 and ≥30 y). Then, participants in each block will be randomly allocated into two groups. Randomization will be done by the use of computer software.

Settings and conduct

Among patients with polycystic ovary syndrome referred to Naghavi outpatient Clinic affiliated to Kashan 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: Individuals with androgen-secreting tumors, CVD and diabetes, thyroid dysfunction, and pregnant women.

Intervention groups

Intervention group: 250 mg magnesium oxide (21st Century, Arizona, USA) + 220 mg of zinc sulfate (Alhavi Pharmaceutical Company, Tehran, Iran) daily, for 12 weeks orally. Control group: Placebo, daily, for 12 weeks orally.

Main outcome variables

Outcomes: Markers of insulin metabolism (primary outcomes) and lipid profiles and gene expression related to insulin and lipid (secondary outcomes) will be quantified at study baseline and end-of-trial.

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20170513033941N40**
Registration date: **2018-10-31, 1397/08/09**
Registration timing: **retrospective**

Last update: **2019-09-15, 1398/06/24**
Update count: **1**

Registration date

2018-10-31, 1397/08/09

Registrant information

Name

Mohammadreza Sharif

Name of organization / entity

Country

Iran (Islamic Republic of)

Phone

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Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2018-07-31, 1397/05/09

Expected recruitment end date

2018-08-15, 1397/05/24

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

The effects of combined zinc and magnesium supplementation on metabolic profiles and gene expression related to insulin and lipid in women with polycystic ovary syndrome

Public title

Effect of combined zinc and magnesium supplementation in treatment of women with polycystic ovary syndrome

Purpose

Treatment

Inclusion/Exclusion criteria

Inclusion criteria:

Patients with polycystic ovary syndrome Individuals aged 18 to 40 years.

Exclusion criteria:

Androgen-secreting tumors cardiovascular diseases and diabetes Pregnant women Thyroid dysfunction

Age

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

Gender

Female

Phase

3

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, all participants will have stratified randomization according to BMI (<25 and ≥25 kg/m2) and age (<30 and ≥30 y). Then, participants in each block will be randomly 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

Randomization and allocation will be concealed from the researchers and participants until the final analyses are completed. Another person at Naghavi outpatient clinic, who is not involved in the trial and not aware of random sequences, will be assigned the participants to the numbered bottles of capsules

Placebo

Used

Assignment

Parallel

Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee

Ethics committee of Kashan University of Medical Sciences

Street address

Ghotbe Ravandi Boulevard, Kashan

City

Kashan

Province

Isfehan

Postal code

1771844351

Approval date

2018-07-30, 1397/05/08

Ethics committee reference number

IR.KAUMS.MEDNT.REC.1397.026

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

Insulin resistance

Timepoint

At the beginning of the study and after 12 weeks of intervention

Method of measurement

Calculation using HOMA formula

2

Description

Insulin

Timepoint

At the beginning of the study and after 12 weeks of intervention

Method of measurement

Elisa kit

Secondary outcomes

1

Description
Total cholesterol
Timepoint
At the beginning of the study and after 12 weeks of intervention
Method of measurement
Enzymatic kit

2

Description
HDL
Timepoint
At the beginning of the study and after 12 weeks of intervention
Method of measurement
Enzymatic kit

3

Description
Triglycerides
Timepoint
At the beginning of the study and after 12 weeks of intervention Triglycerides
Method of measurement
Enzymatic kit

4

Description
Expressed levels of PPAR-γ gene
Timepoint
At the beginning of the study and after 12 weeks of intervention
Method of measurement
PCR

5

Description
Expressed levels of GLUT-1 gene
Timepoint
At the beginning of the study and after 12 weeks of intervention
Method of measurement
PCR

6

Description
Expressed levels of LDL-R gene
Timepoint
At the beginning of the study and after 12 weeks of intervention
Method of measurement
PCR

Intervention groups

1

Description
Intervention group: 250 mg magnesium oxide (21st Century, Arizona, USA) + 220 mg of zinc sulfate (Alhavi Pharmaceutical Company, Tehran, Iran) daily, for 12 weeks orally
Category
Treatment - Drugs

2

Description
Control group: Placebo, daily, for 12 weeks orally.
Category
Placebo

Recruitment centers

1

Recruitment center
Name of recruitment center
Naghavi outpatient Clinic
Full name of responsible person
Dr. Fatemeh Foroozafard
Street address
Shahid Rajaee Avenue, Kashan
City
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Isfehan
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1771844351
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Email
forozanfar_f@kaums.ac.ir

Sponsors / Funding sources

1

Sponsor
Name of organization / entity
Vice chancellor for research, Kashan University of Medical Sciences
Full name of responsible person
Gholamali Hamidi
Street address
Ghotbe Ravandi Boulevard, Kashan
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Phone
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Gholamali_h@kaums.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, Kashan 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
PhD of Nutrition
Latest degree
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Other areas of specialty/work
Nutrition
Street address
Ghotbe Ravandi Boulevard, Kashan
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Person responsible for updating data

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Web page address

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