

Clinical Trial Protocol

Iranian Registry of Clinical Trials

04 Aug 2026

Clinical trial of the effect of combined magnesium and vitamin E supplementation compared with the placebo on metabolic profiles 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 vitamin E supplementation on metabolic profiles in patients with polycystic ovary syndrome (PCOS).

Design

Randomization and allocation will be concealed from the researchers and participants until the final analyses are completed. Another person at Kosar 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.

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: The intake of magnesium and vitamin E supplements within the past 3 months and metabolic disorders.

Intervention groups

Intervention group: 250 mg magnesium (21st Century, Arizona, USA) and 400 IU vitamin E (Zahravi, Tabriz, Iran) daily for 12 weeks orally. Control group: Placebo capsule (Barij Essence, Kashan, Iran), daily for 12 weeks orally.

Main outcome variables

Outcomes: Markers of insulin metabolism (primary outcomes) and lipid profile (secondary outcomes) will be quantified at study baseline and end-of-trial.

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT2017090133941N18**

Registration date: **2017-10-29, 1396/08/07**

Registration timing: **registered_while_recruiting**

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

Update count: **1**

Registration date

2017-10-29, 1396/08/07

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

2017-10-16, 1396/07/24

Expected recruitment end date

2017-10-30, 1396/08/08

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Clinical trial of the effect of combined magnesium and vitamin E supplementation compared with the placebo on metabolic profiles in women with polycystic ovary syndrome

Public title

Effect of combined magnesium and vitamin E 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:

The intake of magnesium and vitamin E supplements within the past 3 months Metabolic disorders

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, after balanced blocked randomisation, all 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

Randomization and allocation will be concealed from the researchers and participants until the final analyses are completed. Another person at Kosar 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 Arak University of Medical Sciences

Street address

Sardasht Avenue, Vice chancellor for research, Arak University of Medical Sciences

City

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Province

Markazi

Postal code

3817793163

Approval date

2017-10-15, 1396/07/23

Ethics committee reference number

IR.ARAKMU.REC.1396.120

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

Timepoint

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

Method of measurement

Elisa kit

2**Description**

Insulin resistance

Timepoint

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

Method of measurement

Calculation using HOMA formula

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**

Triglycerides

Timepoint

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

Method of measurement

Enzymatic kit

3**Description**

HDL

Timepoint

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

Method of measurement

Enzymatic kit

4**Description**

LDL

Timepoint

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

Method of measurement

Enzymatic kit

5**Description**

FPG

Timepoint

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

Method of measurement

Enzymatic kit

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

Intervention group: 250 mg magnesium (21st Century, Arizona, USA) and 400 IU vitamin E (Zahravi, Tabriz, Iran) daily for 12 weeks orally.

Category

Treatment - Drugs

2**Description**

Control group: Placebo capsule (Barij Essence, Kashan, Iran), daily 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

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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

Full name of responsible person

Zatollah Asemi

Position

Ph.D of Nutrition

Latest degree

Ph.D.

Other areas of specialty/work

Nutrition

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Phone

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