Clinical Trial Protocol
Iranian Registry of Clinical Trials

26 Jun 2026

Clinical trial of the effect of combined magnesium and vitamin E supplementation compared with the placebo on hormonal profiles, inflammatory factors and oxidative stress biomarkers in women with polycystic ovary syndrome

Protocol summary

Summary

Objective: The aim of this study is to determine the effects of combined magnesium and vitamin E supplementation on hormonal profiles, inflammatory factors and oxidative stress biomarkers in patients with polycystic ovary syndrome. Study design: Parallel double-blind (both patients and researchers) clinical trial. Randomization will be done by the use of computer-generated random numbers. Inclusion criteria: Patients with polycystic ovary syndrome aged 18 to 40 years. Exclusion criteria: Unwillingness to cooperate. Population and sample size: Among patients with polycystic ovary syndrome referred to Kosar Clinic affiliated to Arak University of Medical Sciences, 60 patients will be selected according to inclusion and exclusion criteria. Intervention: Patients will be assigned into two groups to receive combined magnesium and vitamin E supplements (n=30) or placebo (n=30). 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. Outcomes: Total testosterone (primary outcome) and biomarkers of inflammation and oxidative stress (secondary outcome) will be quantified at study baseline and end-of-trial.

General information

Acronym

IRCT registration information

IRCT registration number: **IRCT2017082733941N8**
Registration date: **2017-09-19, 1396/06/28**
Registration timing: **retrospective**

Last update:
Update count: **0**

Registration date

2017-09-19, 1396/06/28

Registrant information

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Mohammadreza Sharif
Name of organization / entity
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Recruitment status

Recruitment complete

Funding source

Vice chancellor for research, Arak University of Medical Sciences

Expected recruitment start date

2017-08-15, 1396/05/24

Expected recruitment end date

2017-08-30, 1396/06/08

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 hormonal profiles, inflammatory factors and oxidative stress biomarkers 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: Unwillingness to cooperate
Age
From **18 years** old to **40 years** old
Gender
Female

Phase
N/A
Groups that have been masked
No information
Sample size
Target sample size: **60**
Randomization (investigator's opinion)
Randomized
Randomization description
Blinding (investigator's opinion)
Double blinded
Blinding description
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
Arak
Postal code
Approval date
2017-08-14, 1396/05/23
Ethics committee reference number
IR.ARAKMU.REC.1396.88

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
Total testosterone
Timepoint
At the beginning of the study and after 12 weeks of intervention
Method of measurement
Elisa kit

Secondary outcomes

1

Description
SHBG
Timepoint
At the beginning of the study and after 12 weeks of intervention
Method of measurement
Elisa kit

2

Description
Hs-CRP
Timepoint
At the beginning of the study and after 12 weeks of intervention
Method of measurement
Elisa kit

3

Description
Nitric oxide
Timepoint
At the beginning of the study and after 12 weeks of intervention
Method of measurement
Spectrophotometry

4

Description
Malondialdehyde
Timepoint
At the beginning of the study and after 12 weeks of intervention
Method of measurement
Spectrophotometry

5

Description

Glutathione

Timepoint

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

Method of measurement

Spectrophotometry

6

Description

Total antioxidant capacity

Timepoint

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

Method of measurement

Spectrophotometry

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

Maryam Shokrpour

Street address

Emam Khomeyni Avenue, Arak

City

Arak

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

Street address

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

City

Arak

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

empty

Domestic or foreign origin

empty

Category of foreign source of funding

empty

Country of origin

Type of organization providing the funding

empty

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

Other areas of specialty/work

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Sharing plan

Deidentified Individual Participant Data Set (IPD)

empty

Study Protocol

empty

Statistical Analysis Plan

empty

Informed Consent Form

empty

Clinical Study Report

empty

Analytic Code

empty

Data Dictionary

empty