Clinical Trial Protocol
Iranian Registry of Clinical Trials

16 Sep 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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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

2017-08-15, 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
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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