

# Clinical Trial Protocol

## Iranian Registry of Clinical Trials

08 Jun 2026

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

#### Protocol summary

##### Study aim

The aim of this study is to determine the effects of combined magnesium and zinc supplementation on metabolic and genetic profiles in patients of polycystic ovary syndrome (PCOS).

##### Design

Randomized controlled clinical trial, Parallel, double-blind, 60 patients, phase 3

##### Settings and conduct

Population and sample size: Among patients with PCOS referred to Naghavi Clinic affiliated to Kashan University of Medical Sciences, 60 patients will be selected according to inclusion and exclusion criteria.

##### Participants/Inclusion and exclusion criteria

Inclusion criteria: Patients with PCOS according to Rotterdam criteria and aged 18–40 years old will be included in this study. Exclusion criteria: Pregnant during the intervention, metabolic disorders, including androgen-secreting tumors, thyroid dysfunction, diabetes, insulin injection and taking anti-inflammatory drugs

##### Intervention groups

Patients will be assigned into two groups to receive combined magnesium and zinc (n=30) or placebo (n=30). Combined magnesium and zinc, and placebo capsules are similar in shape and size. At the beginning and end of the intervention: 3 months.

##### Main outcome variables

Inflammatory markers (primary outcome) and biomarkers of oxidative stress (secondary outcome) will be quantified at study baseline and end-of-trial.

#### General information

##### Reason for update

##### Acronym

##### IRCT registration information

IRCT registration number: **IRCT201706075623N121**

Registration date: **2017-06-11, 1396/03/21**

Registration timing: **retrospective**

Last update: **2019-09-21, 1398/06/30**

Update count: **1**

##### Registration date

2017-06-11, 1396/03/21

##### Registrant information

###### Name

Zatollah Asemi

###### Name of organization / entity

Kashan University of Medical Sciences

###### Country

Iran (Islamic Republic of)

###### Phone

+98 36 1534 3570

###### Email address

asemi\_z@kaums.ac.ir

##### Recruitment status

**Recruitment complete**

##### Funding source

Vice chancellor for research, Kashan University of Medical Sciences

##### Expected recruitment start date

2017-06-01, 1396/03/11

##### Expected recruitment end date

2017-06-06, 1396/03/16

##### 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 zinc supplementation compared with the placebo on metabolic profiles in women with polycystic ovary syndrome

**Public title**

Effect of supplementation in treatment of women with polycystic ovary syndrome

**Purpose**

Treatment

**Inclusion/Exclusion criteria****Inclusion criteria:**

Aged 18–40 years old Patients with PCOS according to Rotterdam criteria

**Exclusion criteria:**

Pregnant during the intervention Metabolic disorders, including androgen-secreting tumors, thyroid dysfunction, diabetes insulin injection Taking anti-inflammatory drugs

**Age**

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

**Gender**

Female

**Phase**

3

**Groups that have been masked**

- Participant
- Care provider
- Outcome assessor

**Sample size**

Target sample size: **60**

**Randomization (investigator's opinion)**

Randomized

**Randomization description**

At study baseline and after stratification for pre-intervention BMI and age, subjects will be randomly divided into two groups to take either combined magnesium and zinc supplementation (n=30) or placebo (n=30). Randomization will be done by the use of computer-generated random numbers.

**Blinding (investigator's opinion)**

Double blinded

**Blinding description**

Participants, investigators or the assessors of the outcomes are unaware of the study groups.

**Placebo**

Used

**Assignment**

Parallel

**Other design features**

ط

**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**

Isfahan

**Postal code**

1771844351

**Approval date**

2017-05-31, 1396/03/10

**Ethics committee reference number**

IR.Kaums.REC.1396.44

**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**

Hs-CRP

**Timepoint**

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

**Method of measurement**

Elisa kit

**2****Description**

Expressed levels of IL-1 gene

**Timepoint**

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

**Method of measurement**

PCR

**3****Description**

Expressed levels of IL-8 gene

**Timepoint**

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

**Method of measurement**

PCR

**4**

Description

Expressed levels of TNF- $\alpha$  gene

**Timepoint**

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

**Method of measurement**

PCR

## Secondary outcomes

### 1

**Description**

Total antioxidant

**Timepoint**

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

**Method of measurement**

Spectrophotometry

### 2

**Description**

Glutathione

**Timepoint**

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

**Method of measurement**

Spectrophotometry

### 3

**Description**

Nitric oxide

**Timepoint**

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

**Method of measurement**

Spectrophotometry

### 4

**Description**

Expressed levels of TGF- $\beta$  gene

**Timepoint**

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

**Method of measurement**

PCR

### 5

**Description**

Expressed levels of VEGF gene

**Timepoint**

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

**Method of measurement**

PCR

### 6

**Description**

Malondialdehyde

### **Timepoint**

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

### **Method of measurement**

Spectrophotometry

## 7

### **Description**

Protein carbonyl

### **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 220 mg zinc daily (Alhavi, Isfahan, Iran), for 12 weeks orally.

#### **Category**

Treatment - Drugs

### 2

#### **Description**

Control group: Placebo capsule daily (Barij Essence, Kashan, Iran), for 12 weeks orally.

#### **Category**

Treatment - Drugs

## Recruitment centers

### 1

#### **Recruitment center**

##### **Name of recruitment center**

Naghavi Clinic

##### **Full name of responsible person**

Zatollah Asemi

##### **Street address**

Ghotbe Ravandi Boulevard, Kashan

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+98 31 5546 3378

##### **Email**

asemi\_z@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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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**  
Ph.D.

**Other areas of specialty/work**  
Nutrition

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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)**

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