# Clinical Trial Protocol
# Iranian Registry of Clinical Trials

06 Jul 2026

## The effect of magnesium supplements on clinical and metabolic variables in women with polycystic ovarian syndrome (PCOS)

### Protocol summary

**Study aim**

The aim of this study was to evaluate the effect of magnesium supplementation on clinical and metabolic variables in women with PCOS referring to Ayatollah Mousavi Hospital in 1998.

**Design**

Patients will be grouped according to the Balanced Block Randomization method in groups A and B.The sample number will be 20 in each group. The study will be three-way blind

**Settings and conduct**

Patients will be grouped according to the Balanced Block Randomization method into two groups: A and B ، in the magnesium group, magnesium oxide supplement and in the control group only placebo will be administered. Data collection and data analysis are unclear

**Participants/Inclusion and exclusion criteria**

Inclusion criteria: 1. Patients with polycystic ovary syndrome based on the Rotterdam Diagnostic Criteria2. Satisfaction with attending the study3. Satisfaction to continue cooperation4. Magnesium does not have a high base normal. 5. There is no history of electrolyte abnormalities associated with potassium or calcium in the patient.Exclusion criteria: 1. Have any use of magnesium contraindications 2. Supplementation within 3 months prior to study 3. Oral contraceptive use within 3 months prior to study4. Thyroid dysfunction5. HyperprolactinemiaDiabetes Mellitus7. Congenital adrenal hyperplasia8. Drugs that affect adrenal and ovarian function and metabolism of carbohydrates and lipids.9. A history of electrolyte abnormalities associated with potassium and calcium

**Intervention groups**

In the magnesium group, magnesium oxide supplements will be administered to patients, and in the control group, only placebo, produced by the same company, with the same form of magnesium coupling, will be ِadministered daily to patients.

**Main outcome variables**

If magnesium supplements are effective in the treatment of pco, this supplement can be used to treat patients

### General information

**Reason for update**

**Acronym**

**IRCT registration information**

IRCT registration number: **IRCT20200115046147N1**
Registration date: **2020-02-01, 1398/11/12**
Registration timing: **registered_while_recruiting**

Last update: **2020-02-01, 1398/11/12**
Update count: **0**

**Registration date**

2020-02-01, 1398/11/12

**Registrant information**

**Name**

Shabnam Shahmoradi

**Name of organization / entity**

**Country**

Iran (Islamic Republic of)

**Phone**

+98 24 3344 0932

**Email address**

ashkanghadimi23@gmail.com

**Recruitment status**

**Recruitment complete**

**Funding source**

**Expected recruitment start date**

2020-01-28, 1398/11/08

**Expected recruitment end date**

2020-02-04, 1398/11/15

**Actual recruitment start date**

empty

**Actual recruitment end date**

empty

**Trial completion date**
empty

**Scientific title**
The effect of magnesium supplements on clinical and metabolic variables in women with polycystic ovarian syndrome (PCOS)

**Public title**
The effect of magnesium supplements on polycystic ovarian syndrome (PCOS)

**Purpose**
Treatment

**Inclusion/Exclusion criteria**

**Inclusion criteria:**
1. Patients with polycystic ovary syndrome based on the Rotterdam Diagnostic Criteria2. Satisfaction with attending the study3. Satisfaction to continue cooperation4. Magnesium does not have a high base normal.5. There is no history of electrolyte abnormalities associated with potassium or calcium in the patient.

**Exclusion criteria:**

**Age**
From **18 years** old to **35 years** old

**Gender**
Female

**Phase**
3

**Groups that have been masked**

- Participant
- Care provider
- Investigator
- Outcome assessor
- Data analyser

**Sample size**
Target sample size: **40**

**Randomization (investigator's opinion)**
Randomized

**Randomization description**
Balanced Block Randomization

**Blinding (investigator's opinion)**
Triple blinded

**Blinding description**
Patients are treated with prescribed medication packages by the study supervisor (supervisor). The drug packages are quite similar in form and the patient and the planner are not aware of the contents of the packages. In addition, information is collected, the patients are evaluated and the forms are completed by the planner and his assistant who are not aware of the contents of the packages; The data analysis will also be performed by the design consultant and design consultant who is unaware of the contents of the drug packages and only the patient group (group 1 or 2) is identified to analyze the data, so the study is three-blind

**Placebo**
Used

**Assignment**
Parallel

**Other design features**

## Secondary Ids

empty

## Ethics committees

### 1

**Ethics committee**

**Name of ethics committee**
Ethics committee of Zanjan University of Medical Sciences

**Street address**
Gavazang Road - Ayatollah Mousavi Hospital

**City**
zanjan

**Province**
Zanjan

**Postal code**
4513956183

**Approval date**
2019-10-14, 1398/07/22

**Ethics committee reference number**
IR.ZUMS.REC.1398.314

## Health conditions studied

### 1

**Description of health condition studied**
polycystic ovarian syndrome (PCOS)

**ICD-10 code**

**ICD-10 code description**

## Primary outcomes

### 1

**Description**
Changes in Insulin Resistance Index (HOMA-IR)

**Timepoint**
FBS and serum insulin are re-administered to patients at baseline and after 2 months of treatment (end of treatment).

**Method of measurement**
ice.Patients receive fasting insulin for a 12-hour fasting blood sample to measure fasting blood sugar (for diabetes screening).

## Secondary outcomes

### 1

**Description**
Weight Loss and Blood Glucose and Lipid Profile and Blood Pressure and Menstrual Cycle Adjustment in Magnesium Supplemented Patients

**Timepoint**
After 2 months of treatment (end of treatment), weight, waist circumference, blood pressure, menstrual pattern and serum levels of FBS, TG, CHOL, LDL, HDL and insulin are monitored again for two months after completion.

Patients will be monitored for clinical symptoms including menstruation, weight, waist circumference and blood pressure.

**Method of measurement**

The pattern of menstrual periods is recorded in a questionnaire designed for the duration and duration of bleeding during the menstrual cycle. After fasting for 12 hours, a blood sample was taken to measure fasting blood sugar (for diabetes screening), fasting insulin and Mg levels, as well as TG, CHOL, HDL and LDL. People are included in the study who do not have high normal magnesium levels. Weight in fasting, without shoes, with minimal clothing and measured using the Seca Digital Balance with a accuracy of 0.1 kg. Height is measured with the help of a tape measure with a accuracy of 0.1 cm. BMI is calculated by dividing the weight in kilograms by the power of 2 heights per meter. Waist circumference greater than 5 cm above the navel and hip circumference less than 5 cm below the navel are measured with tape measure. Patients' blood pressure is measured and recorded with a single device.

## Intervention groups

### 1

**Description**

Intervention group: In the magnesium group, magnesium oxide supplement made by Galen's company in the form of 250 mg a day for two months will be given to patients and in the control group only placebo produced by the same company with the same form of magnesium catabolic The patient will be prescribed daily.

**Category**

Treatment - Drugs

### 2

**Description**

Control group: In the control group, only placebo, manufactured by Galen's company, in the same form as magnesium chelate, will be administered daily to patients for two months.

**Category**

Treatment - Drugs

## Recruitment centers

### 1

**Recruitment center**

**Name of recruitment center**
Ayatollah Mousavi Hospital

**Full name of responsible person**
Shabnam Shahmoradi

**Street address**
Gavazang Road - Mousavi Hospital

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zanjan

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## Sponsors / Funding sources

### 1

**Sponsor**

**Name of organization / entity**
Zanjan University of Medical Sciences

**Full name of responsible person**
Alireza Shoghli

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info@zums.ac.ir

**Grant name**

**Grant code / Reference number**

**Is the source of funding the same sponsor organization/entity?**
Yes

**Title of funding source**
Zanjan 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**
Zanjan University of Medical Sciences

**Full name of responsible person**
Shabnam Shahmoradi

**Position**
Resident obstetrics and gynecology

**Latest degree**
Medical doctor

**Other areas of specialty/work**
Gynecology and Obstetrics

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## Person responsible for scientific inquiries

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## Person responsible for updating data

**Contact**
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**Full name of responsible person**
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**Latest degree**
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**Other areas of specialty/work**
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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