

# Clinical Trial Protocol

## Iranian Registry of Clinical Trials

19 Jun 2026

### Clinical trial of the effect of multi mineral-vitamin D 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 multi mineral-vitamin D supplementation on metabolic profiles in patients of polycystic ovary syndrome (PCOS).

##### Design

Study design: Parallel double-blind (both patients and researchers) clinical trial. Randomization will be done by the use of computer-generated random numbers.

##### Settings and conduct

Population and sample size: Among patients with PCOS referred to Kosar Clinic affiliated to Arak 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 aged 18 to 40 years. Exclusion criteria: Intake of magnesium, zinc, calcium and/or vitamin D supplements within the past 3 months, pregnant women, metabolic disorders, including hyperandrogenism, Cushing's syndrome, androgen secreting tumors, hyperprolactinemia, thyroid dysfunction and not residing in Arak area.

##### Intervention groups

Intervention: Patients will be assigned into two groups to receive multi mineral-vitamin D (n=30) or placebo (n=30). Multi mineral-vitamin D and placebos capsules are similar in shape and size.

##### Main outcome variables

Outcomes: Markers of insulin metabolism and hormonal profiles (primary outcomes) and lipid profiles, biomarkers of inflammation and 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: **IRCT201701165623N103**

Registration date: **2017-01-22, 1395/11/03**

Registration timing: **registered\_while\_recruiting**

Last update: **2019-09-22, 1398/06/31**

Update count: **1**

##### Registration date

2017-01-22, 1395/11/03

##### 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, Arak University of Medical Sciences

##### Expected recruitment start date

2017-01-12, 1395/10/23

##### Expected recruitment end date

2017-02-01, 1395/11/13

##### Actual recruitment start date

empty

##### Actual recruitment end date

empty

##### Trial completion date

empty

## Scientific title

Clinical trial of the effect of multi mineral-vitamin D 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:

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

### Exclusion criteria:

Intake of magnesium, zinc, calcium and/or vitamin D supplements within the past 3 months. Pregnant women Metabolic disorders, including hyperandrogenism, Cushing's syndrome, androgen secreting tumors, hyperprolactinemia. Thyroid dysfunction Not residing in Arak area

## 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

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

## Secondary Ids

empty

## Ethics committees

### 1

#### Ethics committee

##### Name of ethics committee

Ethics committee of Arak University of Medical

Sciences

## Street address

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

## City

Arak

## Province

Markazi

## Postal code

3814113634

## Approval date

2017-01-11, 1395/10/22

## Ethics committee reference number

IR.ARAKMU.REC.1395.325

## Health conditions studied

### 1

#### Description of health condition studied

Polycystic ovary syndrome

#### ICD-10 code

E28.2

#### ICD-10 code description

Polycystic ovary 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

### 3

#### Description

Fasting plasma glucose

#### Timepoint

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

#### Method of measurement

Enzymatic kit

### 4

#### Description

Total testosterone

**Timepoint**

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

**Method of measurement**

Elisa kit

**5****Description**

SHBG

**Timepoint**

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

**Method of measurement**

Elisa kit

**Secondary outcomes****1****Description**

Triglycerides

**Timepoint**

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

**Method of measurement**

Enzymatic kit

**2****Description**

Total cholesterol

**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**

Total antioxidant

**Timepoint**

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

**Method of measurement**

Spectrophotometry

**5****Description**

Nitric oxide

**Timepoint**

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

**Method of measurement**

Spectrophotometry

**6****Description**

Glutathione

**Timepoint**

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

**Method of measurement**

Spectrophotometry

**7****Description**

Hs-CRP

**Timepoint**

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

**Method of measurement**

Elisa kit

**8****Description**

VLDL

**Timepoint**

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

**Method of measurement**

Elisa kit

**9****Description**

LDL

**Timepoint**

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

**Method of measurement**

Elisa kit

**10****Description**

Malondialdehyde

**Timepoint**

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

**Method of measurement**

Spectrophotometry

**11****Description**

Hirsutism

**Timepoint**

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

**Method of measurement**

Clinical observation

## Intervention groups

### 1

#### Description

Intervention group: Multi mineral-vitamin D supplements (Vitane, Wolfratshausen, Germany), 400 mg calcium, 100 mg magnesium, 4 mg zinc, 200 IU vitamin D3, daily, for 12 weeks orally.

#### Category

Treatment - Drugs

### 2

#### Description

Control group: Placebo capsule, 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 Maktabi

##### Street address

Emam Khomeyni Avenue, Arak

##### City

Arak

##### Province

Markazi

##### Postal code

3814113634

##### Phone

+98 86 3223 3823

##### Email

maktabi.m@yahoo.com

## Sponsors / Funding sources

### 1

#### Sponsor

##### Name of organization / entity

Vice chancellor for research, Arak University of Medical Sciences

##### Full name of responsible person

Mohammad Rafiee

##### Street address

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

##### City

Arak

##### Province

Markazi

##### Postal code

3814113634

#### Phone

+98 86 3223 3823

#### Email

rafiee-m@aums.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, 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

PhD of Nutrition

##### Latest degree

Ph.D.

##### Other areas of specialty/work

Nutrition

##### Street address

Ghotbe Ravandi Boulevard, Kashan

##### City

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##### Province

Isfahan

##### Postal code

81151-87159

##### Phone

+98 31 5546 3378

##### Email

asemi\_z@kaums.ac.ir

## Person responsible for scientific inquiries

#### Contact

##### Name of organization / entity

Kashan University of Medical Sciences

##### Full name of responsible person

Zatollah Asemi

##### Position

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##### Latest degree

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**Web page address****Person responsible for updating data****Contact****Name of organization / entity**

Kashan University of Medical Sciences

**Full name of responsible person**

Zatollah Asemi

**Position**

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**Latest degree**

Ph.D.

**Other areas of specialty/work**

Nutrition

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**City**

Kashan

**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