

# Clinical Trial Protocol

## Iranian Registry of Clinical Trials

01 Jun 2026

### Clinical trial of the effect of vitamin D supplementation compared with the placebo on metabolic profiles and gene expression related to insulin and lipid in women with polycystic ovary syndrome candidate for IVF

#### Protocol summary

##### Study aim

Objective: The aim of this study is to determine the effects of vitamin D supplementation on metabolic profiles and gene expression related to insulin and lipid in patients with polycystic ovary syndrome candidate for IVF.

##### Design

Study design: Randomized double-blind placebo-controlled trial. Randomization will be done by the use of computer-generated random numbers. Patients will be assigned into two groups to receive vitamin D supplements (n=20) or placebo (n=20).

##### Settings and conduct

Among patients with polycystic ovary syndrome candidate for IVF referred to Naghavi Clinic affiliated to Kashan University of Medical Sciences, 40 patients will be selected according to inclusion and exclusion criteria. Participants, investigators or the assessors of the outcomes are unaware of the study groups. Supplements and placebos are similar in shape and size. Fasting blood samples will be taken at baseline and 8 weeks after the intervention. At the beginning and the end of the intervention: 8 weeks.

##### Participants/Inclusion and exclusion criteria

Inclusion criteria: Patients with polycystic ovary syndrome candidate for IVF aged 18 to 40 years.  
Exclusion criteria: Thyroid disorder, diabetes or impaired glucose tolerance.

##### Intervention groups

Intervention group: 50000 IU vitamin D every 2 weeks (Zahravi, Tabriz, Iran), for 8 weeks orally. Control group: Placebo (Barij Essence, Kashan, Iran) every 2 weeks, for 8 weeks orally.

##### Main outcome variables

Outcomes: Markers of insulin metabolism (primary outcomes) and lipid profiles and gene expression related to insulin and lipid (secondary outcomes) will be

quantified at study baseline and end-of-trial.

#### General information

##### Reason for update

##### Acronym

##### IRCT registration information

IRCT registration number: **IRCT20170513033941N27**

Registration date: **2018-01-15, 1396/10/25**

Registration timing: **retrospective**

Last update: **2019-09-15, 1398/06/24**

Update count: **1**

##### Registration date

2018-01-15, 1396/10/25

##### Registrant information

##### Name

Mohammadreza Sharif

##### Name of organization / entity

##### Country

Iran (Islamic Republic of)

##### Phone

+98 31 5546 3378

##### Email address

ostadmohammadi-vr@kaums.ac.ir

##### Recruitment status

**Recruitment complete**

##### Funding source

##### Expected recruitment start date

2017-12-26, 1396/10/05

##### Expected recruitment end date

2018-01-10, 1396/10/20

##### Actual recruitment start date

empty

##### Actual recruitment end date

empty

## Trial completion date

empty

## Scientific title

Clinical trial of the effect of vitamin D supplementation compared with the placebo on metabolic profiles and gene expression related to insulin and lipid in women with polycystic ovary syndrome candidate for IVF

## Public title

Effect of vitamin D supplementation in treatment of patients with polycystic ovary syndrome candidate for IVF

## Purpose

Treatment

## Inclusion/Exclusion criteria

### Inclusion criteria:

Inclusion criteria: Patients with polycystic ovary syndrome. Individuals aged 18 to 40 years.

### Exclusion criteria:

Thyroid disorder Diabetes or impaired glucose tolerance

## 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: **40**

## Randomization (investigator's opinion)

Randomized

## Randomization description

At study baseline, after balanced randomisation, subjects will be allocated into two groups to receive supplement or placebo. 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 Kashan University of Medical Sciences

#### Street address

Ghotbe Ravandi Boulevard, Kashan

#### City

Kashan

#### Province

Isfahan

#### Postal code

8115187159

#### Approval date

2017-12-25, 1396/10/04

#### Ethics committee reference number

IR.KAUMS.MEDNT.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

Insulin

#### Timepoint

At the beginning of the study and after 8 weeks of intervention

#### Method of measurement

Elisa kit

### 2

#### Description

Insulin resistance

#### Timepoint

At the beginning of the study and after 8 weeks of intervention

#### Method of measurement

Calculation using HOMA formula

## Secondary outcomes

### 1

#### Description

Total cholesterol

#### Timepoint

At the beginning of the study and after 8 weeks of intervention

#### Method of measurement

Enzymatic kit

## 2

### **Description**

HDL

### **Timepoint**

At the beginning of the study and after 8 weeks of intervention

### **Method of measurement**

Enzymatic kit

## 3

### **Description**

Triglycerides

### **Timepoint**

At the beginning of the study and after 8 weeks of intervention

### **Method of measurement**

Enzymatic kit

## 4

### **Description**

Expressed levels of PPAR- $\gamma$  gene

### **Timepoint**

At the beginning of the study and after 8 weeks of intervention

### **Method of measurement**

PCR

## 5

### **Description**

Expressed levels of GLUT-1 gene

### **Timepoint**

At the beginning of the study and after 8 weeks of intervention

### **Method of measurement**

PCR

## 6

### **Description**

Expressed levels of LDL-R gene

### **Timepoint**

At the beginning of the study and after 8 weeks of intervention

### **Method of measurement**

PCR

## **Intervention groups**

### 1

#### **Description**

Intervention group: 50000 IU vitamin D every 2 weeks (Zahravi, Tabriz, Iran), for 8 weeks orally.

#### **Category**

Treatment - Drugs

### 2

#### **Description**

Control group: Placebo (Barij Essence, Kashan, Iran) every 2 weeks, for 8 weeks orally.

#### **Category**

Placebo

## **Recruitment centers**

### 1

#### **Recruitment center**

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

Naghavi Clinic

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

Dr. Foroozanfard

##### **Street address**

Shahid Rajaee Avenue, Kashan

##### **City**

Kashan

##### **Province**

Isfahan

##### **Postal code**

8115187159

##### **Phone**

+98 31 5546 3378

##### **Email**

foroosanfar\_f@kaums.ac.ir

## **Sponsors / Funding sources**

### 1

#### **Sponsor**

##### **Name of organization / entity**

Kashan University of Medical Sciences

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

Gholamali Hamidi

##### **Street address**

Ghotbe Ravandi Boulevard, Kashan

##### **City**

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##### **Phone**

+98 31 5546 3378

##### **Email**

hamidi\_gh@kaums.ac.ir

#### **Grant name**

#### **Grant code / Reference number**

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

Yes

#### **Title of funding source**

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**

Nutritionist

**Latest degree**

Ph.D.

**Other areas of specialty/work**

Nutrition

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**Contact**

**Name of organization / entity**

Kashan University of Medical Sciences

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**Postal code**

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**Phone**

**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