

# Clinical Trial Protocol

## Iranian Registry of Clinical Trials

27 May 2026

### Compare The Effect of Vitamin D3 With 2 Different Doses on Metabolic Disorders in Women With Poly-cystic Ovary Syndrome and Vitamin D Deficiency.

#### Protocol summary

##### Summary

This study is a prospective and randomized single-blind clinical trial. The aim of this study is to compare the effect of vitamin D3 with 2 different doses on metabolic disorders in women with polycystic ovary syndrome and vitamin D deficiency. Total of sample size is 124 woman with ages: 18-45 years old. The patients with malabsorption, chronic renal failure, cirrhosis, pancreatitis, nephrotic syndrome, cancer, hyperprolactinemia, cushing's syndrome, congenital adrenal hyperplasia, androgen secreting tumors and pregnant and lactating patients will be excluded. The patients are randomly divided into two groups. Patients do not know about the protocol of the study and type of drug. First group receives oral dose of 50,000 IU of vitamin D once per week for 8 weeks. Second group receives oral dose of 50,000 IU of vitamin D once per month for 2 months. In both methods, 1000 mg of calcium carbonate are given twice daily throughout the treatment period. Patients basic information such as age and BMI, serum triglyceride, LDL, HDL, total cholesterol, fasting blood sugar, fasting insulin levels, vitamin D will be recorded in both groups before treatment and after the treatment period.

#### General information

##### Acronym

##### IRCT registration information

IRCT registration number: **IRCT2015100824426N1**

Registration date: **2015-10-22, 1394/07/30**

Registration timing: **retrospective**

Last update:

Update count: **0**

##### Registration date

2015-10-22, 1394/07/30

#### Registrant information

##### Name

Leila Moradi

##### Name of organization / entity

Ahvaz Jundishapur University of Medical Sciences

##### Country

Iran (Islamic Republic of)

##### Phone

+98 61 3222 2922

##### Email address

moradi.l@ajums.ac.ir

#### Recruitment status

##### Recruitment complete

#### Funding source

Ahvaz Jundishapur University of Medical Sciences

#### Expected recruitment start date

2015-05-31, 1394/03/10

#### Expected recruitment end date

2015-10-02, 1394/07/10

#### Actual recruitment start date

empty

#### Actual recruitment end date

empty

#### Trial completion date

empty

#### Scientific title

Compare The Effect of Vitamin D3 With 2 Different Doses on Metabolic Disorders in Women With Poly-cystic Ovary Syndrome and Vitamin D Deficiency.

#### Public title

The Effect of Vitamin D3 on Metabolic Disorders in Women With Ovarian Cysts and Vitamin D Deficiency

#### Purpose

Treatment

#### Inclusion/Exclusion criteria

Inclusion Criteria: Women with poly-cystic ovary

syndrome; vitamin D less than 30 ng/ml . Exclusion Criteria: Chronic diseases such as malabsorption, chronic renal failure, cirrhosis, pancreatitis, nephrotic syndrome; malignancies; hyperprolactinemia; cushing's syndrome; congenital adrenal hyperplasia; androgen secreting tumors; using Drugs that affect metabolic parameters such as metformin, corticosteroids in the previous three months; using vitamin D and calcium and multivitamins in the last six months.

**Age**

From **18 years** old to **45 years** old

**Gender**

Female

**Phase**

3

**Groups that have been masked**

*No information*

**Sample size**

Target sample size: **124**

**Randomization (investigator's opinion)**

Randomized

**Randomization description****Blinding (investigator's opinion)**

Single blinded

**Blinding description****Placebo**

Not used

**Assignment**

Parallel

**Other design features**

To randomization: Consecutive odd and even numbers are assigned to patients. oral dose of 50,000 IU of vitamin D once per week for 8 weeks and oral dose of 50,000 IU of vitamin D once per month for 2 months are administered to odd and even numbered, respectively.

**Secondary Ids**

empty

**Ethics committees****1****Ethics committee****Name of ethics committee**

Ethics Committee of Ahvaz Jundishapur University Of Medical Sciences

**Street address**

Ground Floor, Central Library, Ahvaz Jundishapur University of Medical Sciences, GolestanBLvd., Ahvaz

**City**

Ahvaz

**Postal code****Approval date**

2015-05-30, 1394/03/09

**Ethics committee reference number**

ir.ajums.REC.1394.16

**Health conditions studied****1****Description of health condition studied**

Vitamin D

**ICD-10 code**

E55.9

**ICD-10 code description**

Avitaminosis D

**Primary outcomes****1****Description**

Body mass index (BMI)

**Timepoint**

Before treatment and after completion of treatment in the eighth week

**Method of measurement**

By Using the formula: weight (kg) / the square of the height (m)

**2****Description**

The level of vitamin D

**Timepoint**

Before treatment and after completion of treatment in the eighth week

**Method of measurement**

Venous sampling and sent to the laboratory

**3****Description**

The serum levels of triglycerides, LDL, HDL, Total cholesterol

**Timepoint**

Before treatment and after completion of treatment in the eighth week

**Method of measurement**

Venous sampling and sent to the laboratory

**4****Description**

Fasting blood glucose levels

**Timepoint**

Before treatment and after completion of treatment in the eighth week

**Method of measurement**

Venous sampling and sent to the laboratory

**5****Description**

Fasting insulin levels

**Timepoint**

Before treatment and after completion of treatment in the eighth week

**Method of measurement**

Venous sampling and sent to the laboratory

## Secondary outcomes

empty

## Intervention groups

### 1

#### Description

Group I: Prescription oral dose of 50,000 IU of vitamin D once per week for 8 weeks.

#### Category

Treatment - Drugs

### 2

#### Description

Group II: Prescription oral dose of 50,000 IU of vitamin D once per month for 2 months.

#### Category

Treatment - Drugs

## Recruitment centers

### 1

#### Recruitment center

##### Name of recruitment center

Khomeini Hospital

##### Full name of responsible person

Bahman Ghaderian

##### Street address

Khomeini Hospital, Shahid Ahvazian St., Ahvaz

##### City

Ahvaz

### 2

#### Recruitment center

##### Name of recruitment center

Golestan Hospital

##### Full name of responsible person

Mahmod Latifi

##### Street address

Golestan Hospital, Farvardin st., Golestan, Ahvaz

##### City

Ahvaz

## Sponsors / Funding sources

### 1

#### Sponsor

##### Name of organization / entity

Vice chancellor For Research Of Ahvaz Jundishapur University of Medical Sciences

##### Full name of responsible person

Nader Saki

##### Street address

Vice chancellor For Research Of Ahvaz Jundishapur University of Medical Sciences, Ground Floor, Central Library, Ahvaz Jundishapur University of Medical

Sciences, GolestanBLvd., Ahvaz

##### City

Ahvaz

##### 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 Of Ahvaz Jundishapur 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

Ahvaz Jundishapur University of Medical Sciences

##### Full name of responsible person

Leila Moradi

##### Position

fellowship in endocrinology and metabolic diseases

##### Other areas of specialty/work

##### Street address

Ahvaz Jundishapur University of Medical Sciences, GolestanBLvd., Ahvaz

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## Person responsible for scientific inquiries

#### Contact

##### Name of organization / entity

Ahvaz Jundishapur University of Medical Sciences

##### Full name of responsible person

Homeira Rashidi

##### Position

Subspecialty Endocrinology and Metabolism

##### Other areas of specialty/work

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

Ahvaz Jundishapur University of Medical Sciences

**Full name of responsible person**

Sanaz Nazari

**Position**

Nurse Anesthesia

**Other areas of specialty/work****Street address**Ahvaz Jundishapur University of Medical Sciences,  
GolestanBLvd., Ahvaz**City****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*