

# Clinical Trial Protocol

## Iranian Registry of Clinical Trials

13 Jun 2026

### Clinical and laboratory Effects of vitamin D supplementation in adolescent with polycystic ovarian syndrome and vitamin D deficiency

#### Protocol summary

##### Summary

Objective: To determine the effect of vitamin D in adolescents with polycystic ovary syndrome have vitamin D deficiency. Design, Setting and conduct: Random; alternating block method; single-blind; two intervention and control groups. Inclusion criteria: age 14 to 18 years old; people with impaired ovulation or anovulation for oligoovulation (oligo- and / or anovulation); 2 and 3 Hyperandrogenemia clinical hyperandrogenism or There polycystic ovarian morphology on ultrasound and they are deficient in vitamin D, and the study Azargoon et al(1) known as polycystic ovarian syndrome. Exclusion criteria: people who do not have full consent to participate in this study; Those who did not use vitamin D to regular weekly; Those in the intervention of the symptoms of polycystic ovary syndrome drugs such as birth control pills, metformin, medroxyprogesterone and progesterone intramuscular injection except in the event of amenorrhea has 45 days from the previous cycle dose of 200 mg for the induction periods are used. Intervention and main outcome measures: In the intervention group, weekly 50000 units of vitamin D and the control group, the placebo treatment in both groups 8 weeks will be (based on studies of Thomson et al. 2012); intervention, in the first day of bleeding, weekly and then monthly up to 8 weeks to two months continues. Methods of collecting data with demographic questions, blood pressure and check list data obtained from in vitro assays (FBS and fasting insulin, TG, HDL and LH, FSH, testosterone and 25 hydroxyvitamin D3) and clinical (hirsutism, acne, menstrual pattern) and ultrasound done.

#### General information

##### Acronym

##### IRCT registration information

IRCT registration number: **IRCT2016021125732N2**

Registration date: **2016-05-01, 1395/02/12**

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

Last update:

Update count: **0**

##### Registration date

2016-05-01, 1395/02/12

##### Registrant information

###### Name

Alireza Emadi

###### Name of organization / entity

Semnan University of Medical Sciences, Semnan, Iran

###### Country

Iran (Islamic Republic of)

###### Phone

+98 23 3345 1336

###### Email address

are20935@semums.ac.ir

##### Recruitment status

**Recruitment complete**

##### Funding source

Deputy of research and technology Semnan University of Medical Sciences

##### Expected recruitment start date

2016-01-21, 1394/11/01

##### Expected recruitment end date

2016-08-20, 1395/05/30

##### Actual recruitment start date

empty

##### Actual recruitment end date

empty

##### Trial completion date

empty

##### Scientific title

Clinical and laboratory Effects of vitamin D supplementation in adolescent with polycystic ovarian syndrome and vitamin D deficiency

**Public title**

Clinical and laboratory Effects of vitamin D supplementation in adolescent with polycystic ovarian syndrome and vitamin D deficiency

**Purpose**

Treatment

**Inclusion/Exclusion criteria**

Inclusion criteria: age 14 to 18 years old; people with impaired ovulation or anovulation for oligoovulation (oligo- and / or anovulation); 2 and 3 Hyperandrogenemia clinical hyperandrogenism or There polycystic ovarian morphology on ultrasound and they are deficient in vitamin D, and the study Azargoon et al(1) known as polycystic ovarian syndrome. Exclusion criteria: people who do not have full consent to participate in this study; Those who did not use vitamin D to regular weekly; Those in the intervention of the symptoms of polycystic ovary syndrome drugs such as birth control pills, metformin, medroxyprogesterone and progesterone intramuscular injection except in the event of amenorrhea has 45 days from the previous cycle dose of 200 mg for the induction periods are used.

**Age**

From **80 years** old to **76 years** old

**Gender**

Female

**Phase**

2-3

**Groups that have been masked**

*No information*

**Sample size**

Target sample size: **50**

**Randomization (investigator's opinion)**

N/A

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

Single blinded

**Blinding description****Placebo**

Used

**Assignment**

Parallel

**Other design features****Secondary Ids**

empty

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

Ethics Committee of the Semnan University of Medical sciences

**Street address**

Semnan University of Medical Sciences

**City**

Semnan

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

2015-08-25, 1394/06/03

**Ethics committee reference number**

IR.SEMUMS.REC.1394.76

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

Adolescent with polycystic ovarian syndrome and vitamin D deficiency

**ICD-10 code**

E28.2 ; E2

**ICD-10 code description**

Polycystic ovarian syndrome; Ovarian dysfunction, unspecified

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

Measuring vitamin D

**Timepoint**

Started

**Method of measurement**

Laboratory - using the kit for measuring vitamin D, with EUROIMMUN, the UK

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

Ultrasonography

**Timepoint**

In 3 to 5 days of menstrual bleeding

**Method of measurement**

Abdominal Ultrasonography, by one sonographer

**2****Description**

Measuring vitamin D

**Timepoint**

After the intervention

**Method of measurement**

Laboratory - using the kit for measuring vitamin D, with EUROIMMUN, the UK

**3****Description**

Blood pressure measurement

**Timepoint**

After the intervention

**Method of measurement**

Manometer using a pan with 710 made in Taiwan, the left arm in a sitting position

#### 4

##### **Description**

Measure weight

##### **Timepoint**

After the intervention

##### **Method of measurement**

Scales with 100 g

#### 5

##### **Description**

Measuring stature

##### **Timepoint**

After the intervention

##### **Method of measurement**

Using tape measure with an accuracy of one centimeter

### **Intervention groups**

#### 1

##### **Description**

In the intervention group, 50 000 IU of vitamin D weekly for 8 weeks will be given. PCOS symptoms, patients should not interfere with effective drugs such as oral contraceptives COCS, metformin, medroxyprogesterone and so on. The only injectable progesterone injections in case of amenorrhea has 45 days from the previous cycle dose of 200 mg intramuscularly for induction menstruation is used.

##### **Category**

Prevention

#### 2

##### **Description**

The control group, placebo will be given for 8 weeks. PCOS symptoms, patients should not interfere with effective drugs such as oral contraceptives COCS, metformin, medroxyprogesterone and so on. The only injectable progesterone injections in case of amenorrhea has 45 days from the previous cycle dose of 200 mg intramuscularly for induction menstruation is used.

##### **Category**

Prevention

### **Recruitment centers**

#### 1

##### **Recruitment center**

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

Hospital AmirAlMomenin Semnan

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

Dr Mojgan Rahmadian

###### **Street address**

Hospital AmirAlMomenin, Mostafa Khomeini Blvd,  
Semnan

###### **City**

Semnan

### **Sponsors / Funding sources**

#### 1

##### **Sponsor**

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

Vice Chancellor for Research, Semnan University of  
Medical sciences

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

Dr Mojgan Rahmadian

###### **Street address**

Hospital AmirAlMomenin, Mostafa Khomeini Blvd,  
Semnan

###### **City**

Semnan

##### **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, Semnan 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**

Semnan University of Medical Sciences, Vice  
Chancellor for Research, Semnan

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

Dr Mojgan Rahmadian

###### **Position**

Obstetrics and Gynecology

###### **Other areas of specialty/work**

###### **Street address**

Hospital AmirAlMomenin, Mostafa Khomeini Blvd,  
Semnan

###### **City**

Semnan

###### **Postal code**

3514799442

###### **Phone**

+98 23 3345 1336

###### **Fax**

+98 23 3344 8950

###### **Email**

are20935@gmail.com

###### **Web page address**

## Person responsible for scientific inquiries

### Contact

**Name of organization / entity**

Semnan University of Medical Sciences

**Full name of responsible person**

Dr Mojgan Rahmaniaan

**Position**

Obstetrics and Gynecology

**Other areas of specialty/work****Street address**

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## Person responsible for updating data

### Contact

**Name of organization / entity**

Semnan University of Medical Sciences

**Full name of responsible person**

Dr Mojgan Rahmaniaan

**Position**

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## 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*