

# Clinical Trial Protocol

## Iranian Registry of Clinical Trials

10 Jun 2026

### Assessment of vitamin D oral supplementation on insulin resistance, visceral fat and adiponectin in women with polycystic ovary syndrome and hypovitaminosis D

#### Protocol summary

##### Summary

**Object:** Assessment of vitamin D oral supplementation on insulin resistance, visceral fat and Adiponectin in women with polycystic ovary syndrome and hypovitaminosis D  
**Design:** Single-blind randomized clinical trial (in patient).  
**Methods:** We conducted a single-blind (in patients), randomized clinical trial. Forty-four women are selected with baseline polycystic ovary syndrome. Participants were randomly assigned to two groups: The intervention group (8 vitamin D3 capsule 50000 IU during 2 month (1 capsule in the week after lunch) and the Control group: 8 placebo capsule (Paraffinedible) during 2 month (1 capsule in the week after lunch). ELISA, HOMA-IR, HOMA-B, ECL, QUICKI methods was used for data analysis.  
**Inclusion criteria:** Women with pcos according rotterdam criteria; Vitamin D deficiency ( $x \leq 20$  ng); OCPs consumer; Age between 20 to 38. **Exclude criteria:** Under 20 and over 38 years old; Neoplastic disorders; hepatic, renal; cardiovascular; malabsorptive and pregnancy; Those who consume vitamin D and taking antidiabetic drugs; People who follow a special diet pattern had specific physical activity  
**Variables:** Insulin resistant; visceral fat; adiponectin were measured and compared between two groups before and the end of intervention period. Also 24 recall and exposure to sunlight questioner during the intervention were completed. **Intervention/Control:** Intervention: 8 vitamin D3 capsule 50000 IU during 2 month (1 capsule in the week after lunch ). Control: 8 placebo capsule (Paraffinedible) during 2 month (1 capsule in the week after lunch)

#### General information

##### Acronym

##### IRCT registration information

IRCT registration number: **IRCT2016101030248N1**  
Registration date: **2016-11-17, 1395/08/27**

Registration timing: **retrospective**

Last update:

Update count: **0**

##### Registration date

2016-11-17, 1395/08/27

##### Registrant information

###### Name

Sakineh Nouri saeidlou

###### Name of organization / entity

Urmia University of Medical Sciences

###### Country

Iran (Islamic Republic of)

###### Phone

+98 44 3276 6825

###### Email address

nourisaeidlou\_s@umsu.ac.ir

##### Recruitment status

**Recruitment complete**

##### Funding source

government

##### Expected recruitment start date

2016-05-21, 1395/03/01

##### 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

Assessment of vitamin D oral supplementation on insulin resistance, visceral fat and adiponectin in women with polycystic ovary syndrome and hypovitaminosis D

**Public title**

Assessment of vitamin D oral supplementation on insulin resistance, visceral fat and adiponectin in women with polycystic ovary syndrome and hypovitaminosis D

**Purpose**

Supportive

**Inclusion/Exclusion criteria**

Inclusion criteria: Women with pcos according rotterdam criteria; Vitamin D deficiency ( $x < 20$  ng); OCPs consumer; Age between 20 to 38 Exclude criteria: Under 20 and over 38 years old; Neoplastic disorders; hepatic; renal; cardiovascular; malabsorptive and pregnancy; Those who consume vitamin D and taking antidiabetic drugs; People who follow a special diet pattern had specific physical activity

**Age**

From **20 years** old to **38 years** old

**Gender**

Female

**Phase**

2

**Groups that have been masked**

*No information*

**Sample size**

Target sample size: **44**

**Randomization (investigator's opinion)**

Randomized

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

Single blinded

**Blinding description****Placebo**

Used

**Assignment**

Parallel

**Other design features**

In order to avoid the possible effect of awareness of allocation to treatment or placebo groups a single blind design was used which only researcher was awareness of randomizing into two groups. According to the number's of randomized table, we put patient into two groups and they did not know any things about this.

**Secondary Ids**

empty

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

Ethics committee of Urmia University of Medical Sciences

**Street address**

University Campus: Pardis Nazlou, 11 km of Nazlou Road,Urmia,Iran Phone:+98 44 3223 4897 Fax: +98 44 322 290 59

**City**

Urmia

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

2016-05-18, 1395/02/29

**Ethics committee reference number**

ir.umsu.rec.1395.100

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

Polycystic Ovary Syndrome

**ICD-10 code**

E28.2

**ICD-10 code description**

Sclerocystic ovary syndrome Stein-Leventhal syndrome

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

insulin resistance

**Timepoint**

before intervention-after intervention (2 month later)

**Method of measurement**

insulin resistance: HOMA-IR, HOMA-B ,QUICKI

**2****Description**

visceral fat

**Timepoint**

before intervention-after intervention(2 month later)

**Method of measurement**

visceral fat :BIA(Inbody 770)

**3****Description**

Adiponectin

**Timepoint**

before intervention-after intervention(2 month later)

**Method of measurement**

Adiponectin.: serum adiponectin.

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

Sun exposure and physical activity

**Timepoint**

during intervention

**Method of measurement**

The questionnaire sunlight

**2****Description**

Diet

**Timepoint**

week 4-6-8

**Method of measurement**

24-hour recalls

**Intervention groups****1****Description**

Intervention: 8 vitamin D3 capsule 50000 IU during 2 month (1 capsule in the week after lunch)

**Category**

Treatment - Drugs

**2****Description**

Control: 8 placebo capsule(Paraffinedible) during 2 month (1 capsule in the week after lunch)

**Category**

Placebo

**Recruitment centers****1****Recruitment center****Name of recruitment center**

Shahid Motaharey Hospital

**Full name of responsible person**

Dr. Taherh Behrozey Lak

**Street address****City**

Urmia

**Sponsors / Funding sources****1****Sponsor****Name of organization / entity**

Vice chancellor for research, Urmia University of Medical Sciences

**Full name of responsible person**

Dr Iraj Mohebi

**Street address**

University Campus: Pardis Nazlou, 11 km of Nazlou Road,Urmia,Iran Phone:+98 44 3223 4897 Fax: +98 44 322 290 59

**City**

Urmia

**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, Urmia 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**

Urmia University of Medical Sciences

**Full name of responsible person**

Dr.Sakineh Nouri Saeidlou

**Position**

PhD.Nutrition

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

UMSU Central Site: Orjhans Street, Resalat Blvd, Urmia , Iran (Postal Code:571478334)

**City**

Urmia

**Postal code****Phone**

+98 44 3276 6825

**Fax****Email**

saeedlou2003@yahoo.com;  
nourisaeidlou\_s@umsu.ac.ir

**Web page address****Person responsible for scientific inquiries****Contact****Name of organization / entity**

Urmia University of Medical Sciences

**Full name of responsible person**

Dr. Sakineh Nouri Saeedlou

**Position**

PhD. Nutrition

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

Urmia University of Medical Sciences ,Health Research Center Food & Beverage

**City**

Urmia

**Postal code**

Iran

**Phone**

+98 44 3276 6825

**Fax****Email**

saeedlou2003@yahoo.com;  
nourisaeidlou\_s@umsu.ac.ir

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

**Full name of responsible person**

Maryam Seyed Aboutorabi

**Position**

Student/master

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

Number 17, block 5, sazman abb st , sheykh fazlolah  
free way

**City**

Tehran

**Postal code****Phone**

+98 21 8826 1244

**Fax****Email**

aboutorabi93@gmail.com

**Web page address****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*