

# Clinical Trial Protocol

## Iranian Registry of Clinical Trials

10 Jun 2026

### Effect of oral vitamin D3 supplementation on glycemic parameters, lipid profile, and hs-CRP inflammatory factor in polycystic ovarian syndrome

#### Protocol summary

##### Summary

The aim of this study is to evaluate the effect of vitamin D3 supplementation on glycemic parameters, lipid profile and hs-CRP inflammatory factor in polycystic ovarian syndrome (PCOS). Fifty women with PCOS who are 18-40 years old and meet the inclusion criteria would be recruited from clinics of Tabriz University of medical sciences. The patients are assigned as a double blind manner into placebo or intervention groups based on age and whether consume drugs. The intervention group receive oral vitamin D3 supplement one tablet every 20 days for 60 days (50000 IU vitamin D3/tablet) and the placebo group receive placebo in the same way. 24h dietary recall for 3 days, anthropometric indices, fasting blood sugar, insulin, triglycerides, lipoproteins, Apo A-1, 25(OH)D, parathyroid hormone and hs-CRP are measured at baseline and after intervention.

#### General information

##### Acronym

##### IRCT registration information

IRCT registration number: **IRCT138904113140N2**

Registration date: **2010-07-02, 1389/04/11**

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

Last update:

Update count: **0**

##### Registration date

2010-07-02, 1389/04/11

##### Registrant information

###### Name

Bahram Pourghassem Gargari

###### Name of organization / entity

Health and Nutrition Faculty, Tabriz University of medical sciences

###### Country

Iran (Islamic Republic of)

###### Phone

+98 41 1435 7580

###### Email address

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##### Recruitment status

**Recruitment complete**

##### Funding source

Tabriz university of medical sciences, Nutrition research committee

##### Expected recruitment start date

2010-04-19, 1389/01/30

##### Expected recruitment end date

2010-08-09, 1389/05/18

##### Actual recruitment start date

empty

##### Actual recruitment end date

empty

##### Trial completion date

empty

##### Scientific title

Effect of oral vitamin D3 supplementation on glycemic parameters, lipid profile, and hs-CRP inflammatory factor in polycystic ovarian syndrome

##### Public title

Effect of vitamin D3 supplementation on polycystic ovarian syndrome

##### Purpose

Treatment

##### Inclusion/Exclusion criteria

Inclusion criteria: diagnosis of PCOS based on Rotterdam criteria (presence of two of the three following characteristics: 1. oligomenorrhea /amenorrhea, 2. chemical or clinical finding of hyperandrogenism and 3. polycystic appearance of ovary), voluntary consent for participation in the study, age of 16-40 years, gender: female. Exclusion criteria: Other common causes of hyperandrogenemia and/or anovulation;

hyperprolactinoma, congenital adrenal hyperplasia, Cushing syndrome, and virilizing ovarian or adrenal tumors, diabetes mellitus and heart, kidney and liver dysfunction, using vitamin D or Calcium supplement, metformin or insulin sensitizing drugs, corticosteroids, anticonvulsants during last 2 month or during the study, Smoking, alcohol abuse, breast feeding and pregnancy.

#### Age

From **18 years** old to **40 years** old

#### Gender

Female

#### Phase

2-3

#### Groups that have been masked

*No information*

#### Sample size

Target sample size: **50**

#### Randomization (investigator's opinion)

Randomized

#### Randomization description

#### Blinding (investigator's opinion)

Double blinded

#### Blinding description

#### Placebo

Used

#### Assignment

Parallel

#### Other design features

This study would be done in spring and summer which vitamin D effective UV radiation is the same in 38th latitude.

## Secondary Ids

empty

## Ethics committees

### 1

#### Ethics committee

##### Name of ethics committee

Tabriz university of medical sciences

##### Street address

Tabriz university of medical sciences

##### City

Tabriz

##### Postal code

#### Approval date

empty

#### Ethics committee reference number

8911

## Health conditions studied

### 1

#### Description of health condition studied

Polycystic ovarian syndrome

#### ICD-10 code

E28.2

#### ICD-10 code description

Polycystic ovarian syndrome

## Primary outcomes

### 1

#### Description

improvement of gelycemic parameters

#### Timepoint

60 days

#### Method of measurement

serum level of blood suger and fasting Insulin

### 2

#### Description

lipid profile and hs-CRP

#### Timepoint

60 days

#### Method of measurement

Serum level of HDL, LDL, Total Cholesterol, TG, ApoA1, hs-CRP

### 3

#### Description

serum level of alkaline phosphatase, calcium and phosphorus

#### Timepoint

60 days

#### Method of measurement

serum level

## Secondary outcomes

### 1

#### Description

antropometric indicators (BMI)

#### Timepoint

60 days

#### Method of measurement

Body weight without shoes with calibrated scale, Standing height without shoes are measured. BMI was calculated with this equation:  $W(\text{kg}) / H(\text{m})^2$ .

### 2

#### Description

dietary regime

#### Timepoint

60 days

#### Method of measurement

3 days 24h dietaty racall

## Intervention groups

### 1

#### Description

intervantion group: 50000 IU vitaminD3 every 20 days

for 60 days

**Category**

Treatment - Drugs

**2**

**Description**

control group: placebo every 20 days for 60 days

**Category**

Placebo

**Recruitment centers**

**1**

**Recruitment center**

**Name of recruitment center**

Alzahra Hospital and Pardis clinic

**Full name of responsible person**

**Street address**

**City**

Tabriz

**Sponsors / Funding sources**

**1**

**Sponsor**

**Name of organization / entity**

Research Vice-chancellor of Tabriz University of Medical Sciences and Nutrition Research Center of T

**Full name of responsible person**

Dr Rashidi and Dr Ostadrahimi

**Street address**

Health & Nutrition Faculty, Tabriz university of medical sciences, 3rd floor, Golgasht st, Tabriz

**City**

Tabriz

**Grant name**

**Grant code / Reference number**

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

Yes

**Title of funding source**

Research Vice-chancellor of Tabriz University of Medical Sciences and Nutrition Research Center of T

**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**

Health and Nutrition Faculty, Tabriz university of medical sciences

**Full name of responsible person**

Bahram Pourghassem

**Position**

PhD in Nutrition science

**Other areas of specialty/work**

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Master student of nutrition science

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**Email**  
**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*