Clinical Trial Protocol
Iranian Registry of Clinical Trials

27 Jul 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 sager, 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

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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. oligomemorreha /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 measuredl. BMI was calculated with this equation: W(kg) /H(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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Person responsible for updating data

Contact

Name of organization / entity

Health and Nutrition faculty, Tabriz university of medical sciences

Full name of responsible person

Hania Rahimi

Position

Master student of nutrition science

Other areas of specialty/work

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Health and Nutrition faculty

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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