

Clinical Trial Protocol

Iranian Registry of Clinical Trials

11 Sep 2026

Effect of oral vitamin D3 supplementation on bone biochemical factors, serum magnesium and zinc in polycystic ovary syndrome

Protocol summary

Summary

The aim of this study is to evaluate the effect of vitamin D3 supplementation on bone biochemical factors, serum magnesium and zinc in polycystic ovarian syndrome (PCOS). 54 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 receives 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. Serum alkaline phosphatase, calcium, phosphorus, magnesium and zinc are measured at baseline and after intervention in 2 groups.

General information

Acronym

IRCT registration information

IRCT registration number: **IRCT201201043140N3**

Registration date: **2012-01-13, 1390/10/23**

Registration timing: **retrospective**

Last update:

Update count: **0**

Registration date

2012-01-13, 1390/10/23

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

pourghassemb@tbzmed.ac.ir

Recruitment status

Recruitment complete

Funding source

Student research committee

Expected recruitment start date

2011-04-09, 1390/01/20

Expected recruitment end date

2011-08-01, 1390/05/10

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Effect of oral vitamin D3 supplementation on bone biochemical factors, serum magnesium and zinc in polycystic ovary syndrome

Public title

Effect of oral vitamin D3 supplementation on biochemical factors in polycystic ovary syndrome

Purpose

Supportive

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; female aged 18-40 years. 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

Groups that have been masked

No information

Sample size

Target sample size: **54**

Randomization (investigator's opinion)

Randomized

Randomization description

Blinding (investigator's opinion)

Double 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 Tabriz university of medical sciences

Street address

Research Vice-chancellor, central building, number 2, Tabriz university of medical sciences, Golgasht street

City

Tabriz

Postal code

51665-118

Approval date

2011-12-19, 1390/09/28

Ethics committee reference number

9065

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 bone biochemical factors

Timepoint

before and after intervention (60 days)

Method of measurement

serum levels of alkaline phosphatase, calcium, phosphoruse

2

Description

improvement of serum zinc and magnesium

Timepoint

before and after intervention (60 days)

Method of measurement

serum levels of zinc and magnesium

Secondary outcomes

1

Description

food habits

Timepoint

before and after intervention (60 days)

Method of measurement

3 days 24h dietary recall

2

Description

anthropometric indicator

Timepoint

before and after intervention (60 days)

Method of measurement

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

Intervention groups

1

Description

control group: placebo every 20 days for 60 days

Category

Placebo

2

Description

intervention group: 50000 IU vitaminD3 every 20 days for 60 days

Category

Treatment - Drugs

Recruitment centers

1

Recruitment center

Name of recruitment center

Alzahra Hospital and Pardis clinic

Full name of responsible person

Hania Rahimi

Street address

Artesh street

City

Tabriz

Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Student research committee

Full name of responsible person

Dr. Saeed Pirouz Panah

Street address

Health & Nutrition Faculty, Tabriz university of
medical sciences, Golgasht st.

City

Tabriz

Grant name

Grant code / Reference number

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

Yes

Title of funding source

Student research committee

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

Hania Rahini

Position

student

Other areas of specialty/work

Street address

Health & Nutrition Faculty, Tabriz university of
medical sciences, Golgasht st.

City

Tabriz

Postal code

Phone

+98 41 1330 4779

Fax

Email

hania.rahimi@gmail.com

Web page address

Person responsible for scientific inquiries

Contact

Name of organization / entity

Health & Nutrition Faculty, Tabriz university of
medical sciences

Full name of responsible person

Hania Rahimi

Position

student

Other areas of specialty/work

Street address

Health & Nutrition Faculty, Tabriz university of
medical sciences, Golgasht st.

City

Tabriz

Postal code

Phone

+98 41 1330 4779

Fax

Email

hania.rahimi@gamil.com

Web page address

Person responsible for updating data

Contact

Name of organization / entity

Full name of responsible person

Neda Seyed Sadjadi

Position

Other areas of specialty/work

Street address

City

Postal code

Phone

Fax

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