Clinical Trial Protocol
Iranian Registry of Clinical Trials

22 Nov 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

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Name of organization / entity

Health and Nutrition Faculty, Tabriz University of medical sciences

Country

Iran (Islamic Republic of)

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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. oligomemorreha /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 dietaty racall

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 measuredl. 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
intervantion 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
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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