Clinical Trial Protocol
Iranian Registry of Clinical Trials

02 Nov 2026

Effect of calcium plus vitamin D supplementation on insulin resistance in patients with poly-cystic ovary syndrome and vitamin D deficiency

Protocol summary

Summary

Effect of calcium plus vitamin D supplementation on insulin resistance in patients with poly-cystic ovary syndrome and vitamin D deficiency. Design: single-blind clinical, randomized in available, two intervention and control groups. Inclusion criteria: women 18 to 40 years old with polycystic ovary syndrome and a lack of vitamin D. Exclusion criteria: patients with Cushing's syndrome; congenital adrenal hyperplasia; hyperprolactinemia; hypothyroidism; hyperthyroidism; androgen-secreting tumors; Severe vitamin D deficiency (<10 ng/ml); all the diseases that affect the level of vitamin D; such as kidney disease and liver. The main outcome variables, interventions: 60 eligible patients referred to the clinics of Semnan University of Medical Sciences were enrolled in the study. and Demographic information and testing sessions have been collected and tested by HOMA-IR and FAI calculated randomly into two groups: 1) Intervention: treatment with vitamin D and calcium (50,000 IU weekly, supplemental vitamin D and 1000 mg daily supplement calcium orally for 8 weeks); 2) the control group. After 8 weeks, demographic information, and the tests were evaluated and the index is calculated by HOMA-IR and FAI.

General information

Acronym

IRCT registration information

IRCT registration number: **IRCT2016122625732N10**
Registration date: **2017-02-19, 1395/12/01**
Registration timing: **registered_while_recruiting**

Last update:
Update count: **0**

Registration date

2017-02-19, 1395/12/01

Registrant information

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Recruitment status

Recruitment complete

Funding source

Semnan University of Medical Sciences

Expected recruitment start date

2016-09-22, 1395/07/01

Expected recruitment end date

2017-03-20, 1395/12/30

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Effect of calcium plus vitamin D supplementation on insulin resistance in patients with poly-cystic ovary syndrome and vitamin D deficiency

Public title

Effect of calcium plus vitamin D supplementation on insulin resistance in patients with poly-cystic ovary syndrome and vitamin D deficiency

Purpose

Prevention

Inclusion/Exclusion criteria

Inclusion criteria: women 18 to 40 years old with polycystic ovary syndrome and a lack of vitamin D.

Exclusion criteria: patients with Cushing's syndrome; congenital adrenal hyperplasia; hyperprolactinemia; hypothyroidism; hyperthyroidism; androgen-secreting tumors; Severe vitamin D deficiency (<10 ng/ml); all the diseases that affect the level of vitamin D; such as kidney disease and liver.

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

Gender
Female

Phase
N/A

Groups that have been masked
No information

Sample size
Target sample size: **60**

Randomization (investigator's opinion)
Randomized

Randomization description

Blinding (investigator's opinion)
Single blinded

Blinding description

Placebo
Not used

Assignment
Parallel

Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee
Ethics Committee of the Semnan University of Medical sciences

Street address
Semnan University of Medical Sciences, Basij Blvd, Semnan

City
semnan

Postal code
3514799442

Approval date
2016-09-13, 1395/06/23

Ethics committee reference number
IR.SEMUMS.REC.1395.123

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
Vitamin D

Timepoint
The beginning and end of the study

Method of measurement
Experiment

2

Description
Calcium

Timepoint
The beginning and end of the study

Method of measurement
Experiment

Secondary outcomes

empty

Intervention groups

1

Description
Control group: there is no intervention in the control group.

Category
Behavior

2

Description
Intervention Groups: to each of the patients in the intervention group, 50,000 units of vitamin D weekly and 1,000 mg daily calcium supplements orally administered for 8 weeks to patients. After 8 weeks of testing re-done.

Category
Prevention

Recruitment centers

1

Recruitment center

Name of recruitment center
Clinics of Semnan University of Medical Sciences

Full name of responsible person
Majid Foroutan

Street address
Semnan University of Medical Sciences, Basij Blvd,Semnan.

City
Semnan

Sponsors / Funding sources

1

Sponsor
Name of organization / entity
Vice Chancellor for Research and Technology, Semnan University of Medical Sciences
Full name of responsible person
Dr Mohammad Reza Asgari
Street address
Semnan University of Medical Sciences, Basij Blvd, Semnan
City
Semnan
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 and Technology, Semnan 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
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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