

Clinical Trial Protocol

Iranian Registry of Clinical Trials

27 Jun 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

Name

Alireza Emadi

Name of organization / entity

Semnan University of Medical Sciences, Semnan, Iran

Country

Iran (Islamic Republic of)

Phone

+98 23 3345 1336

Email address

are20935@semums.ac.ir

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**

Semnan University of Medical Sciences

Full name of responsible person

Majid Foroutan

Position

Endocrinologist

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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