

Clinical Trial Protocol

Iranian Registry of Clinical Trials

29 Jul 2026

Clinical trial of the effect of vitamin D supplementation compared with the placebo on metabolic profiles in women with polycystic ovary syndrome

Protocol summary

Summary

Objective: The aim of this study is to determine the effects of vitamin D supplementation on metabolic profiles in patients of polycystic ovary syndrome (PCOS) with insulin resistance. Study design: Parallel double-blind (both patients and researchers) clinical trial. Randomization will be done by the use of computer-generated random numbers. Inclusion criteria: Patients with PCOS according to Rotterdam criteria aged 18 to 40 years. Exclusion criteria: Unwillingness to cooperate. Population and sample size: Among patients with PCOS referred to Naghavi Clinic affiliated to Kashan University of Medical Sciences, 105 patients will be selected according to inclusion and exclusion criteria. Intervention: Patients will be assigned into three groups to receive vitamin D with dosage of 4000 IU (n=35) or vitamin D with dosage of 1000 IU (n=35) or placebo (n=35). Vitamin D supplements and placebo capsules are similar in shape and size. Fasting blood samples will be taken at baseline and 12 weeks after the intervention. At the beginning and end of the intervention: 3 months. Outcomes: Metabolic profiles will be quantified at study baseline and end-of-trial.

General information

Acronym

IRCT registration information

IRCT registration number: **IRCT201604145623N74**
Registration date: **2016-04-17, 1395/01/29**
Registration timing: **retrospective**

Last update:

Update count: **0**

Registration date

2016-04-17, 1395/01/29

Registrant information

Name

Zatollah Asemi

Name of organization / entity

Kashan University of Medical Sciences

Country

Iran (Islamic Republic of)

Phone

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Email address

asemi_z@kaums.ac.ir

Recruitment status

Recruitment complete

Funding source

Kashan University of Medical Sciences

Expected recruitment start date

2016-02-20, 1394/12/01

Expected recruitment end date

2016-03-15, 1394/12/25

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Clinical trial of the effect of vitamin D supplementation compared with the placebo on metabolic profiles in women with polycystic ovary syndrome

Public title

Effect of supplementation in treatment of women with polycystic ovary syndrome

Purpose

Treatment

Inclusion/Exclusion criteria

Inclusion criteria: Patients with PCOS according to

Rotterdam criteria; aged 18 to 40 years. Exclusion criteria: Unwillingness to cooperate.

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: **105**

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 Kashan University of Medical Sciences

Street address

Ghotbe Ravandi Boulevard, Kashan

City

Kashan

Postal code

Approval date

2016-03-09, 1394/12/19

Ethics committee reference number

IR.Kaums.REC.1394.174

Health conditions studied

1

Description of health condition studied

Polycystic ovary syndrome

ICD-10 code

E28.2

ICD-10 code description

Polycystic ovarian syndrome

Primary outcomes

1

Description

Insulin

Timepoint

At the beginning of the study and after 12 weeks of intervention

Method of measurement

Elisa kit

2

Description

Insulin resistance

Timepoint

At the beginning of the study and after 12 weeks of intervention

Method of measurement

Questionnaire

Secondary outcomes

1

Description

Triglycerides

Timepoint

At the beginning of the study and after 12 weeks of intervention

Method of measurement

Enzymatic kit

2

Description

HDL-cholesterol

Timepoint

At the beginning of the study and after 12 weeks of intervention

Method of measurement

Enzymatic kit

3

Description

Total cholesterol

Timepoint

At the beginning of the study and after 12 weeks of intervention

Method of measurement

Enzymatic kit

4

Description

Testosterone

Timepoint

At the beginning of the study and after 12 weeks of intervention

Method of measurement

Elisa kit

Intervention groups

1

Description

Intervention group: Vitamin D supplements, 4000 IU, daily, for 12 weeks orally.

Category

Treatment - Drugs

2

Description

Intervention group: Vitamin D supplements, 1000 IU, daily, for 12 weeks orally.

Category

Treatment - Drugs

3

Description

Control group: Placebo capsule, daily for 12 weeks orally.

Category

Treatment - Drugs

Recruitment centers

1

Recruitment center

Name of recruitment center

Naghavi Clinic

Full name of responsible person

Zatollah Asemi

Street address

Shahid Rajaei Avenue, Kashan

City

Kashan

Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Vice chancellor for research, Kashan University of Medical Sciences

Full name of responsible person

Gholamali Hamidi

Street address

Ghotbe Ravandi Boulevard, Kashan

City

Kashan

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, Kashan 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

Person responsible for scientific inquiries

Contact

Name of organization / entity

Kashan University of Medical Sciences

Full name of responsible person

Zatollah Asemi

Position

PhD of Nutrition

Other areas of specialty/work

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Person responsible for updating data

Contact

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Full name of responsible person

Zatollah Asemi

Position

PhD of Nutrition

Other areas of specialty/work

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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