Clinical Trial Protocol
Iranian Registry of Clinical Trials

03 Jun 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 eclusion 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 placebos 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 quantifid 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
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Iran (Islamic Republic of)
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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 Rajaee 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

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asemi_z@kaums.ac.ir; asemi_r@yahoo.com
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