Clinical Trial Protocol
Iranian Registry of Clinical Trials

13 Jun 2026

Effects of vitamin D and calcium co-supplementation on insulin resistance and lipid factor in overweight women with polycystic ovary syndrome

Protocol summary

Study aim

The aim of this study is to determine the effects of vitamin D and calcium co-supplementation on insulin resistance and lipid factors in overweight women with polycystic ovary syndrome (PCOS).

Design

Study design: parallel double-blind randomized controlled clinical trial.

Settings and conduct

Population and sample size: 104 women with PCOS eligible and referred to Gynecology Clinic affiliated to Kashan University of Medical Sciences, Kashan, Iran in the study will be selected.

Participants/Inclusion and exclusion criteria

Inclusion criteria: Patients with PCOS according to Rotterdam criteria and aged 18 to 40 years will be included in this study. Exclusion criteria: Neoplastic, hepatic disorders, renal or cardiovascular disorders, malabsorptive disorders, taking calcium and vitamin D within the last 6 months, calcium intake more than 1500 mg per day, using hormone therapy, antidiabetic, or anti-obesity medications within the last 6 months.

Intervention groups

Intervention: Patients will be assigned to receive either 50000 IU vitamin D/week and 1000 mg calcium/d co-supplement (intervention group: n=26), 50000 IU vitamin D/week supplement (intervention group: n=26), 1000 mg/d calcium supplement (intervention group: n=26) or placebo (control group: n=26).

Main outcome variables

Insulin resistance (primary outcome) and lipid profiles (secondary outcome) will be quantified at study baseline and end-of-trial.

General information

Reason for update

Due to an error, the request for an update in our website was conducted after paper published. However, the revisions were accordance with either the original approved proposal or with coordination with Vice Chancellor of Research at the University.

Acronym

IRCT registration information

IRCT registration number: **IRCT201309275623N10**
Registration date: **2013-10-07, 1392/07/15**
Registration timing: **registered_while_recruiting**

Last update: **2019-10-20, 1398/07/28**
Update count: **1**

Registration date

2013-10-07, 1392/07/15

Registrant information

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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

2013-10-02, 1392/07/10

Expected recruitment end date

2013-10-16, 1392/07/24

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title
Effects of vitamin D and calcium co-supplementation on insulin resistance and lipid factor in overweight women with polycystic ovary syndrome

Public title
Effect of supplementation in treatment of polycystic ovary syndrome

Purpose
Treatment

Inclusion/Exclusion criteria

Inclusion criteria:
Patients with PCOS according to Rotterdam criteria Aged 18 to 40 years

Exclusion criteria:
Neoplastic Hepatic disorders Renal or cardiovascular disorders Malabsorptive disorders Taking calcium and vitamin D within the last 6 months Calcium intake more than 1500 mg per day Using hormone therapy, antidiabetic, or anti-obesity medications within the last 6 months

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

Gender
Female

Phase
3

Groups that have been masked

- Participant
- Investigator
- Outcome assessor

Sample size
Target sample size: **104**

Randomization (investigator's opinion)
Randomized

Randomization description
To decrease potential confounding effects, all participants at study baseline and after stratification for pre-intervention BMI and age will be randomly allocated to take either supplement or placebo. Randomization will be done by the use of Stat Trek software.

Blinding (investigator's opinion)
Double blinded

Blinding description
Randomization and allocation will be concealed from the researchers and participants until the final analyses are completed. Another person at the Clinic who is not involved in the trial and not aware of random sequences, will be assigned the participants to the numbered bottles of capsules.

Placebo
Used

Assignment
Parallel

Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee
Kashan University of Medical Sciences

Street address
Bolvare Ghotbe Ravandi, Kashan

City
Kashan

Province
Isfehan

Postal code
8115187159

Approval date
2013-10-01, 1392/07/09

Ethics committee reference number
P/29/5/1/2588

Health conditions studied

1

Description of health condition studied
Polycystic ovary syndrome

ICD-10 code
E28.2

ICD-10 code description
Sclerocystic ovary syndrome Stein-Leventhal syndrome

Primary outcomes

1

Description
Insulin resistance

Timepoint
At the beginning of the study and after 8 weeks of intervention

Method of measurement
Eliza

Secondary outcomes

1

Description
Insulin

Timepoint
At the beginning of the study and after 8 weeks of intervention

Method of measurement
Elisa kit

2

Description
Insulin sensitivity

Timepoint
At the beginning of the study and after 8 weeks of

intervention

Method of measurement

Using QUICKI formula

3

Description

Triglycerides

Timepoint

At the beginning of the study and after 8 weeks of intervention

Method of measurement

Enzymatic kit

4

Description

Total cholesterol

Timepoint

At the beginning of the study and after 8 weeks of intervention

Method of measurement

Enzymatic kit

5

Description

VLDL

Timepoint

At the beginning of the study and after 8 weeks of intervention

Method of measurement

Enzymatic kit

6

Description

LDL-cholesterol

Timepoint

At the beginning of the study and after 8 weeks of intervention

Method of measurement

Enzymatic kit

7

Description

HDL-cholesterol

Timepoint

At the beginning of the study and after 8 weeks of intervention

Method of measurement

Enzymatic kit

Intervention groups

1

Description

Intervention group: Vitamin D perl and calcium capsule, 50000 IU and 1000 mg, weekly and daily, for 8 weeks orally.

Category

Treatment - Drugs

2

Description

Intervention group: Vitamin D perl, 50000 IU, weekly, for 8 weeks orally.

Category

Treatment - Drugs

3

Description

Intervention group: Calcium capsule, 1000 mg, daily, for 8 weeks orally.

Category

Treatment - Drugs

4

Description

Control group: Placebo capsule, daily, for 8 weeks orally.

Category

Treatment - Drugs

Recruitment centers

1

Recruitment center

Name of recruitment center

Gynecology clinic

Full name of responsible person

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Sponsors / Funding sources

1

Sponsor

Name of organization / entity

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Grant name
Grant code / Reference number
Is the source of funding the same sponsor organization/entity?
Yes
Title of funding source
Kashan University of Medical Sciences
Proportion provided by this source
100
Public or private sector
Public
Domestic or foreign origin
Domestic
Category of foreign source of funding
empty
Country of origin
Type of organization providing the funding
Academic

Person responsible for general inquiries

Contact
Name of organization / entity
Kashan University of Medical Sciences
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Position
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Sharing plan

Deidentified Individual Participant Data Set (IPD)
Undecided - It is not yet known if there will be a plan to make this available
Study Protocol
Undecided - It is not yet known if there will be a plan to make this available
Statistical Analysis Plan
Undecided - It is not yet known if there will be a plan to make this available
Informed Consent Form
Undecided - It is not yet known if there will be a plan to make this available
Clinical Study Report
Undecided - It is not yet known if there will be a plan to

make this available

Analytic Code

Undecided - It is not yet known if there will be a plan to make this available

Data Dictionary

Undecided - It is not yet known if there will be a plan to make this available