

Clinical Trial Protocol

Iranian Registry of Clinical Trials

13 Jun 2026

Clinical trial of the effect of combined vitamin D, K and calcium supplementation compared with the placebo on metabolic profiles in women with polycystic ovary syndrome

Protocol summary

Study aim

Objective: The aim of this study is to determine the effects of combined vitamin D, K and calcium supplementation on metabolic profiles in patients of polycystic ovary syndrome (PCOS).

Design

Study design: Parallel double-blind (both patients and researchers) clinical trial. Randomization will be done by the use of computer-generated random numbers.

Settings and conduct

Population and sample size: Among patients with PCOS referred to Akbarabadi gynecology Clinic affiliated to Iran University of Medical Sciences, 60 patients will be selected according to inclusion and exclusion criteria.

Participants/Inclusion and exclusion criteria

Inclusion criteria: Patients with PCOS according to Rotterdam criteria aged 18 to 40 years. Exclusion criteria: Pregnancy, adrenal gland disorders and/or other endocrine diseases and hormonal treatments in the previous 6 months.

Intervention groups

Intervention group: Vitamin D, K and calcium supplements, 400 IU vitamin D+ 180 µg vitamin K+1000 mg calcium (Aryan Salamat, Tehran, Iran), daily, for 8 weeks orally. Control group: Placebo capsule (Barij Essence, Kashan, Iran), daily for 8 weeks orally.

Main outcome variables

Outcomes: Markers of insulin metabolism (primary outcomes) and lipid profiles (secondary outcome) will be quantified at study baseline and end-of-trial.

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT201608115623N87**

Registration date: **2016-08-26, 1395/06/05**

Registration timing: **retrospective**

Last update: **2019-09-24, 1398/07/02**

Update count: **1**

Registration date

2016-08-26, 1395/06/05

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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+98 36 1534 3570

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Recruitment status

Recruitment complete

Funding source

Iran University of Medical Sciences

Expected recruitment start date

2016-07-02, 1395/04/12

Expected recruitment end date

2016-07-04, 1395/04/14

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Clinical trial of the effect of combined vitamin D, K and calcium 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:

Pregnancy Adrenal gland disorders and/or other endocrine diseases and hormonal treatments in the previous 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: **60**

Randomization (investigator's opinion)

Randomized

Randomization description

To decrease potential confounding effects, after balanced blocked randomization, all participants will be allocated into two treatment groups to take either supplementation or placebo. Randomization will be done by the use of Stat Trek software. Participants, investigators or the assessors of the outcomes are also unaware of the study groups.

Blinding (investigator's opinion)

Double blinded

Blinding description

Participants, investigators or the assessors of the outcomes are unaware of the study groups.

Placebo

Used

Assignment

Parallel

Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee

Ethics committee of Iran University of Medical Sciences

Street address

Vice chancellor for research, Iran University of Medical Sciences, Hemmat Highway, Tehran

City

Tehran

Province

Tehran

Postal code

1168743514

Approval date

2016-07-02, 1395/04/12

Ethics committee reference number

IR.IUMS.REC.1395.26361

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 resistance

Timepoint

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

Method of measurement

Questionnaire

2

Description

Serum insulin

Timepoint

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

Method of measurement

Elisa kit

Secondary outcomes

1

Description

Triglycerides

Timepoint

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

Method of measurement

Enzymatic kit

2

Description

Total cholesterol

Timepoint

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

Method of measurement

Enzymatic kit

3

Description

HDL

Timepoint

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

Method of measurement

Enzymatic kit

4

Description

VLDL

Timepoint

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

Method of measurement

Enzymatic kit

5

Description

LDL

Timepoint

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

Method of measurement

Enzymatic kit

6

Description

FPG

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, K and calcium supplements, 400 IU vitamin D+ 180 µg vitamin K+1000 mg calcium (Aryan Salamat, Tehran, Iran), daily, for 8 weeks orally.

Category

Treatment - Drugs

2

Description

Control group: Placebo capsule (Barij Essence, Kashan,

Iran), daily for 8 weeks orally.

Category

Treatment - Drugs

Recruitment centers

1

Recruitment center

Name of recruitment center

Akbarabadi Clinic

Full name of responsible person

Maryam Karamali

Street address

Akbarabadi Hospital, Mowlavi Street, Tehran

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research@IUMS.ac.ir

Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Vice chancellor for research, Iran University of Medical Sciences

Full name of responsible person

Seyed Ali Javad Moosavi

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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

Vice chancellor for research, Iran 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
Full name of responsible person
Zatollah Asemi
Position
PhD of Nutrition
Latest degree
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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