

Clinical Trial Protocol

Iranian Registry of Clinical Trials

18 Sep 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

Country

Iran (Islamic Republic of)

Phone

+98 36 1534 3570

Email address

asemi_z@kaums.ac.ir

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
City
Tehran
Province
Tehran
Postal code
1168743514
Phone
+98 21 5560 6034
Email
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
Street address
Vice chancellor for research, Iran University of Medical Sciences, Hemmat Highway, Tehran
City
Tehran
Province
Tehran
Postal code
1168743514
Phone
+98 21 5560 6034
Email
research@iums.ac.ir
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
Ph.D.
Other areas of specialty/work
Nutrition
Street address
Ghotbe Ravandi Boulevard, Kashan
City
Kashan
Province
Isfahan
Postal code
81151-87159
Phone
+98 31 5546 3378
Email
asemi_z@kaums.ac.ir

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
Latest degree
Ph.D.
Other areas of specialty/work
Nutrition
Street address
Ghotbe Ravandi Boulevard, Kashan
City
Kashan
Province
Isfahan
Postal code
81151-87159
Phone

+98 31 5546 3378

Fax

Email

asemi_r@yahoo.com

Web page address

Person responsible for updating data

Contact

Name of organization / entity
Kashan University of Medical Sciences
Full name of responsible person
Zatollah Asemi
Position
PhD of Nutrition
Latest degree
Ph.D.
Other areas of specialty/work
Nutrition
Street address
Ghotbe Ravandi Boulevard, Kashan
City
Kashan
Province
Isfahan
Postal code
81151-87159
Phone
+98 31 5546 3378
Fax
Email
asemi_r@yahoo.com
Web page address

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