

Clinical Trial Protocol

Iranian Registry of Clinical Trials

11 Oct 2026

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

Protocol summary

Study aim

The aim of the current study is to evaluate the effects of vitamins D, K and calcium supplementation on metabolic profiles in women with polycystic ovary syndrome (PCOS).

Design

Study design: Parallel double-blind (both patients and researchers) randomized controlled clinical trial.

Settings and conduct

Population and sample size: 60 patients with PCOS among women of eligible and referred to Alavi Clinic affiliated to Ardabil University of Medical Sciences, Ardabil, Iran in the study will be selected.

Participants/Inclusion and exclusion criteria

Inclusion criteria: Patients with PCOS according to Rotterdam criteria, higher than 5 years of their disease and aged 18 to 40 years will be included in this study. Exclusion criteria: Pregnant women, elevated levels of prolactin, thyroid disorder, endocrine diseases including diabetes or impaired glucose tolerance, and gastrointestinal problems.

Intervention groups

Intervention: Patients will be assigned to receive either vitamins D, K and calcium supplements (intervention group: n=30) or placebo (control group: n=30).

Main outcome variables

Outcomes: Endocrine biomarkers (primary outcomes) and biomarkers of oxidative stress and inflammation (secondary outcomes) will be quantified at study baseline and end-of-trial.

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT201509015623N51**

Registration date: **2015-09-09, 1394/06/18**

Registration timing: **retrospective**

Last update: **2019-09-25, 1398/07/03**

Update count: **1**

Registration date

2015-09-09, 1394/06/18

Registrant information

Name

Zatollah Asemi

Name of organization / entity

Kashan University of Medical Sciences

Country

Iran (Islamic Republic of)

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Recruitment status

Recruitment complete

Funding source

Ardabil University of Medical Sciences

Expected recruitment start date

2015-08-09, 1394/05/18

Expected recruitment end date

2015-08-30, 1394/06/08

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Clinical trial of the effect of combined vitamins D, K and calcium supplementation 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:
Pregnant woman Elevated levels of prolactin Thyroid disorder Endocrine diseases including diabetes or impaired glucose tolerance, and gastrointestinal problems.

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
At study baseline and after stratification for pre-intervention BMI and age, subjects will be randomly divided into two groups to take combined vitamins D, K and calcium supplementation (n=30) or placebo (n=30). Randomization will be done by the use of computer-generated random numbers.

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 Ardabil University of Medical Sciences

Street address

Ardabil University of Medical Sciences
City
Ardabil
Province
Ardabil
Postal code
00984588884233
Approval date
2015-08-08, 1394/05/17
Ethics committee reference number
IR.ARUMS.REC.1394.16

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

Free testosterone

Timepoint

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

Method of measurement

Elisa kit

2

Description

FSH

Timepoint

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

Method of measurement

Enzymatic kit

3

Description

LH

Timepoint

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

Method of measurement

Enzymatic kit

4

Description

Dehydroepiandrosterone sulfate (DHEAS)

Timepoint

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

Method of measurement

Enzymatic kit

5

Description

Prolactin

Timepoint

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

Method of measurement

Enzymatic kit

Secondary outcomes

1

Description

Total antioxidant

Timepoint

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

Method of measurement

Spectrophotometry

2

Description

hs-CRP

Timepoint

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

Method of measurement

Spectrophotometry

3

Description

Nitric oxide

Timepoint

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

Method of measurement

Spectrophotometry

4

Description

Glutathione

Timepoint

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

Method of measurement

Spectrophotometry

5

Description

Malondialdehyde

Timepoint

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

Method of measurement

Spectrophotometry

Intervention groups

1

Description

Intervention group: Combined vitamins D- K- calcium tablet, 200 IU vitamin D- 90 µg vitamin K- 500 mg calcium, daily, for 8 weeks orally.

Category

Treatment - Drugs

2

Description

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

Category

Treatment - Drugs

Recruitment centers

1

Recruitment center

Name of recruitment center

Alavi Clinic

Full name of responsible person

Maryamalsadat Razavi

Street address

Pasdaran Avenue, Ardabil

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5613974156

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alavi@arums.ac.ir

Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Vice chancellor for research, Ardabil University of Medical Sciences

Full name of responsible person

Sharam Habibzadeh

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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, Ardabil 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

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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