Clinical Trial Protocol
Iranian Registry of Clinical Trials

10 Jun 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 inflamation (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

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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
City
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Ardabil
Postal code
5613974156
Phone
+98 45 8888 4233
Email
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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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asemi_z@kaums.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, 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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Person responsible for updating data

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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