Clinical Trial Protocol
Iranian Registry of Clinical Trials

05 Jun 2026

Clinical trial of the effect of vitamin D supplementation compared with the placebo on metabolic profiles in women with polycystic ovary syndrome

Protocol summary

Study aim
The aim of this study is to determine the effects of vitamin D 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 Kosar Clinic affiliated to Arak University of Medical Sciences, 70 patients will be selected according to inclusion and eclusion criteria.

Participants/Inclusion and exclusion criteria
Inclusion criteria: Patients with phenotype B of PCOS according to Rotterdam criteria and aged 18 to 40 years. Exclusion criteria: Pregnant women, women with endocrine diseases including diabetes or impaired glucose tolerance

Intervention groups
Intervention: Patients will be assigned into two groups to receive vitamin D with dosage of 50000 IU (n=35) or placebo (n=35) every two weeks. Vitamin D supplements and placebos capsules are similar in shape and size.

Main outcome variables
Outcomes: Markers of insulin metabolism and hormonal profiles (primary outcomes) and lipid profiles, biomarkers of inflammation and oxidative stress (secondary outcome) will be quantified at study baseline and end-of-trial.

General information

Reason for update

Acronym

IRCT registration information
IRCT registration number: **IRCT201606115623N82**
Registration date: **2016-07-01, 1395/04/11**
Registration timing: **retrospective**

Last update: **2019-09-23, 1398/07/01**
Update count: **1**

Registration date
2016-07-01, 1395/04/11

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
Vice chancellor for research, Arak University of Medical Sciences

Expected recruitment start date
2016-04-24, 1395/02/05

Expected recruitment end date
2016-05-04, 1395/02/15

Actual recruitment start date
empty

Actual recruitment end date
empty

Trial completion date
empty

Scientific title
Clinical trial of the effect of vitamin D 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 phenotype B of PCOS according to Rotterdam criteria Aged between18 to 40 years old
Exclusion criteria:
Pregnant women Women with endocrine diseases including diabetes or impaired glucose tolerance
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: **70**
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 vitamin D supplementation (n=35) or placebo (n=35). 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 Arak University of Medical Sciences
Street address
Vice chancellor for research, Arak University of Medical Sciences, Sardasht Avenue, Arak
City
Arak
Province
Markazi
Postal code
3814113634
Approval date
2016-04-23, 1395/02/04
Ethics committee reference number
IR.ARAKMU.REC.1395.41

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
Timepoint
At the beginning of the study and after 12 weeks of intervention
Method of measurement
Elisa kit

2

Description
Insulin resistance
Timepoint
At the beginning of the study and after 12 weeks of intervention
Method of measurement
Questionnaire

3

Description
Total testosterone
Timepoint
At the beginning of the study and after 12 weeks of intervention
Method of measurement
Elisa kit

4

Description
SHBG
Timepoint
At the beginning of the study and after 12 weeks of intervention

Method of measurement
Elisa kit

5

Description
Free testosterone
Timepoint
At the beginning of the study and after 12 weeks of intervention
Method of measurement
Elisa kit

Secondary outcomes

1

Description
Total antioxidant
Timepoint
At the beginning of the study and after 12 weeks of intervention
Method of measurement
Spectrophotometry

2

Description
Cholesterol
Timepoint
At the beginning of the study and after 12 weeks of intervention
Method of measurement
Enzymatic kit

3

Description
HDL-cholesterol
Timepoint
At the beginning of the study and after 12 weeks of intervention
Method of measurement
Enzymatic kit

4

Description
hs-CRP
Timepoint
At the beginning of the study and after 12 weeks of intervention
Method of measurement
Spectrophotometry

5

Description
Nitric oxide
Timepoint
At the beginning of the study and after 12 weeks of intervention
Method of measurement
Spectrophotometry

6

Description
Triglycerides
Timepoint
At the beginning of the study and after 12 weeks of intervention
Method of measurement
Enzymatic kit

7

Description
Glutathione
Timepoint
At the beginning of the study and after 12 weeks of intervention
Method of measurement
Enzymatic kit

8

Description
Malondialdehyde
Timepoint
At the beginning of the study and after 12 weeks of intervention
Method of measurement
Enzymatic kit

9

Description
VLDL
Timepoint
At the beginning of the study and after 12 weeks of intervention
Method of measurement
Enzymatic kit

10

Description
Hirsutism
Timepoint
At the beginning of the study and after 12 weeks of intervention
Method of measurement
Clinical observation

Intervention groups

1

Description
Intervention group: Vitamin D supplements, 50000 IU, every two weeks, for 12 weeks orally.
Category
Treatment - Drugs

2

Description
Control group: Placebo capsule, every two weeks for 12 weeks orally.
Category
Placebo

Recruitment centers

1

Recruitment center
Name of recruitment center
Kosar Clinic
Full name of responsible person
Maryam Maktabi
Street address
Emam Khomeyni Avenue, Arak
City
Arak
Province
Markazi
Postal code
3814113634
Phone
+98 86 3223 3823
Email
maktabi.m@yahoo.com

Sponsors / Funding sources

1

Sponsor
Name of organization / entity
Vice chancellor for research, Arak University of Medical Sciences
Full name of responsible person
Mohammad Rafiee
Street address
Vice chancellor for research, Arak University of Medical Sciences, Sardasht Avenue, Arak
City
Arak
Province
Isfehan
Postal code
3814113634
Phone
+98 86 3223 3823
Email
rafiee-m@aums.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, Arak 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
Isfehan
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
Isfehan
Postal code
81151-87159
Phone
+98 31 5546 3378
Fax

Email
asemi_z@kaums.ac.ir
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
Isfehan
Postal code
8115187159
Phone
+98 31 5546 3378
Fax
Email
asemi_z@kaums.ac.ir
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