

Clinical Trial Protocol

Iranian Registry of Clinical Trials

19 Jun 2026

Clinical trial of the effect of vitamin D supplementation compared with the placebo on biomarkers of inflammation and oxidative stress 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 biomarkers of inflammation and oxidative stress in patients of polycystic ovary syndrome (PCOS) with insulin resistance.

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, 90 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: Pregnant during the intervention, androgen secreting tumors, hyperprolactinemia, thyroid dysfunction, diabetes or impaired glucose tolerance.

Intervention groups

Intervention: Patients will be assigned into three groups to receive vitamin D with dosage of 4000 IU (n=30) or vitamin D with dosage of 1000 IU (n=30) or placebo (n=30). Vitamin D supplements and placebos capsules are similar in shape and size.

Main outcome variables

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

General information

Reason for update

Due to an error, the request for an update in our website

was conducted after paper published. However, the revisions were accordance with either the original approved proposal or with coordination with Vice Chancellor of Research at the University.

Acronym

IRCT registration information

IRCT registration number: **IRCT201604145623N75**

Registration date: **2016-04-20, 1395/02/01**

Registration timing: **retrospective**

Last update: **2019-10-18, 1398/07/26**

Update count: **1**

Registration date

2016-04-20, 1395/02/01

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

Arak University of Medical Sciences

Expected recruitment start date

2016-03-07, 1394/12/17

Expected recruitment end date

2016-03-15, 1394/12/25

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 biomarkers of inflammation and oxidative stress in women with polycystic ovary syndrome

Public title
Effect of vitamin D 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 during the intervention Androgen secreting tumors Hyperprolactinemia Thyroid dysfunction 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: **90**

Randomization (investigator's opinion)
Randomized

Randomization description
At study baseline and after balanced blocked randomization, subjects will be randomly divided into three groups. 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
3819693345

Approval date
2016-03-07, 1394/12/17

Ethics committee reference number
IR.ARAKMU.REC.1394.347

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
Total testosterone

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

Method of measurement
Elisa kit

2

Description
Sex hormone-binding globulin

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

Glutathione

Timepoint

At the beginning of the study and after 12 weeks of intervention

Method of measurement

Spectrophotometry

3

Description

Hs-CRP

Timepoint

At the beginning of the study and after 12 weeks of intervention

Method of measurement

Spectrophotometry

4

Description

Nitric oxide

Timepoint

At the beginning of the study and after 12 weeks of intervention

Method of measurement

Spectrophotometry

5

Description

Malondialdehyde

Timepoint

At the beginning of the study and after 12 weeks of intervention

Method of measurement

Spectrophotometry

6

Description

Hirsutism

Timepoint

At the beginning of the study and after 12 weeks of intervention

Method of measurement

Clinical observation

7

Description

Insulin resistance

Timepoint

At the beginning of the study and after 12 weeks of intervention

Method of measurement

Enzymatic kit

Intervention groups

1

Description

Intervention group: Vitamin D supplements, 4000 IU, daily, for 12 weeks orally.

Category

Treatment - Drugs

2

Description

Intervention group: Vitamin D supplements, 1000 IU, daily, for 12 weeks orally.

Category

Treatment - Drugs

3

Description

Control group: Placebo capsule, daily for 12 weeks orally.

Category

Treatment - Drugs

Recruitment centers

1

Recruitment center

Name of recruitment center

Kosar Clinic

Full name of responsible person

Mehri Jamilian

Street address

Emam Khomeyni Avenue, Arak

City

Arak

Province

Markazi

Postal code

3819691187

Phone

+98 38 1969 3345

Email

mjamilian@arakmu.ac.ir

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

Markazi

Postal code

3819693345

Phone

+98 86 3313 6055

Email

info@arakmu.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

Isfahan

Postal code

1771844351

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

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Fax**Email**

asemi_z@kaums.ac.ir

Web page address**Person responsible for updating data****Contact****Name of organization / entity**

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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