Clinical Trial Protocol
Iranian Registry of Clinical Trials

09 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 eclusion 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
Isfehan
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
Zatollah Asemi
Position
PhD of Nutrition
Latest degree
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City
Kashan
Province
Isfehan
Postal code
1771844351
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
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Kashan
Province
Isfehan
Postal code
1771844351
Phone
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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