Clinical Trial Protocol
Iranian Registry of Clinical Trials

18 Sep 2026

Effects of vitamin D and calcium co-supplementation on inflammatory factors and biomarkers of oxidative stress in overweight and deficient vitamin D women with polycystic ovary syndrome

Protocol summary

Study aim

The aim of this study is to determine the effects of vitamin D and calcium co-supplementation on inflammatory factors and biomarkers of oxidative stress in overweight and deficient vitamin D women with polycystic ovary syndrome (PCOS).

Design

Study design: parallel double-blind randomized controlled clinical trial.

Settings and conduct

Population and sample size: 104 women with PCOS eligible and referred to Kossar Clinic affiliated to Arak University of Medical Sciences, Arak, Iran in the study will be selected.

Participants/Inclusion and exclusion criteria

Inclusion criteria: Patients with polycystic ovary syndrome and aged 18 to 40 years will be included in this study. Exclusion criteria: Pregnant or lactating women, taking medicinal treatment of infertility, individuals with diabetes mellitus, taking insulin-sensitizing agents and hormonal treatment involving oestrogen or progesterone within the last 3 months.

Intervention groups

Intervention: Patients will be assigned to receive either 50000 IU vitamin D/week and 1000 mg calcium/d co-supplement (intervention group: n=26), 50000 IU vitamin D/week supplement (intervention group: n=26), 1000 mg/d calcium supplement (intervention group: n=26) or placebo (control group: n=26). Fasting blood samples will be taken at baseline and after 8-wk intervention to measure inflammatory factors and biomarkers of oxidative stress. Start and End Date of Intervention: 8 weeks.

Main outcome variables

Outcomes: HOMA-B (primary outcome) and biomarkers of inflammation and oxidative stress (secondary outcomes) 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: **IRCT201407015623N21**
Registration date: **2014-08-24, 1393/06/02**
Registration timing: **retrospective**

Last update: **2019-10-17, 1398/07/25**
Update count: **1**

Registration date

2014-08-24, 1393/06/02

Registrant information

Name
Zatollah Asemi
Name of organization / entity
Kashan University of Medical Sciences
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Iran (Islamic Republic of)
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Recruitment status

Recruitment complete

Funding source

Arak University of Medical Sciences

Expected recruitment start date

2014-05-22, 1393/03/01

Expected recruitment end date

2014-06-04, 1393/03/14

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Effects of vitamin D and calcium co-supplementation on inflammatory factors and biomarkers of oxidative stress in overweight and deficient vitamin D women with polycystic ovary syndrome

Public title

Effect of supplementation in treatment of polycystic ovary syndrome

Purpose

Treatment

Inclusion/Exclusion criteria

Inclusion criteria:

Patients with PCOS according to Rotterdam criteria Aged 18 to 40 years Overweight (BMI ≥25 kg/m2)

Exclusion criteria:

Pregnant or lactating women Taking medicinal treatment of infertility Individuals with diabetes mellitus Taking insulin-sensitizing agents and hormonal treatment involving oestrogen or progesterone within the last 3 months

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: **104**

Randomization (investigator's opinion)

Randomized

Randomization description

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

Arak University of Medical Sciences

Street address

Vice-chancellor for Education and Research, Sardasht Avenue, Arak

City

Arak

Province

Markazi

Postal code

3819693345

Approval date

2014-05-21, 1393/02/31

Ethics committee reference number

93-166-15

Health conditions studied

1

Description of health condition studied

Polycystic ovary syndrome

ICD-10 code

E28.2

ICD-10 code description

Sclerocystic ovary syndrome Stein-Leventhal syndrome

Primary outcomes

1

Description

HOMA-B

Timepoint

Baseline and End-of-trial

Method of measurement

Elisa

Secondary outcomes

1

Description

Hs-CRP

Timepoint

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

Method of measurement

Elisa kit

2

Description

Plasma malondialdehyde
Timepoint
At the beginning of the study and after 8 weeks of intervention
Method of measurement
Spectrophotometry

3

Description
Plasma total antioxidant capacity
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
Nitric oxide
Timepoint
At the beginning of the study and after 8 weeks of intervention
Method of measurement
Spectrophotometry

6

Description
Catalase
Timepoint
At the beginning of the study and after 8 weeks of intervention
Method of measurement
Spectrophotometry

Intervention groups

1

Description
Intervention group: Vitamin D pearl and calcium capsule, 50000 IU and 1000 mg, weekly and daily, for 8 weeks orally.
Category
Treatment - Drugs

2

Description
Intervention group: Vitamin D pearl, 50000 IU, weekly, for 8 weeks orally.
Category
Treatment - Drugs

3

Description
Intervention group: Calcium capsule, 1000 mg, daily, for 8 weeks orally.
Category
Treatment - Drugs

4

Description
Control group: Placebo capsule, daily, for 8 weeks orally.
Category
Treatment - Drugs

Recruitment centers

1

Recruitment center
Name of recruitment center
Kossar Clinic
Full name of responsible person
Mehri Jamilian
Street address
Emam Khomeyni Avenue, Arak
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8715988141
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Sponsors / Funding sources

1

Sponsor
Name of organization / entity
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Full name of responsible person
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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
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
Nutrition PhD
Latest degree
Ph.D.
Other areas of specialty/work
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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