Clinical Trial Protocol
Iranian Registry of Clinical Trials

09 Jun 2026

Clinical trial of the effect of combined vitamin D and evening primrose oil supplementation on metabolic profiles and oxidative stress in women with polycystic ovary syndrome

Protocol summary

Study aim

Objective: The aim of the current study is to evaluate the effects of combined vitamin D and evening primrose oil supplementation on metabolic profiles and oxidative stress in women with polycystic ovary syndrome (PCOS).

Design

Study design: Parallel double-blind (both patients and researchers) randomized controlled clinical trial. Random assignment will be done by the use of computer-generated random numbers.

Settings and conduct

Population and sample size: 60 patients of eligible and referred to Kosar Clinic affiliated to Arak University of Medical Sciences, Arak, Iran in the study will be selected.

Participants/Inclusion and exclusion criteria

Inclusion criteria: Women aged 18-40 years diagnosed with PCOS.Exclusion criteria: Elevated levels of prolactin, thyroid disorder, endocrine diseases including individuals with diabetes, impaired glucose tolerance, gastrointestinal diseases.

Intervention groups

Intervention group: Combined vitamin D and evening primrose oil pearl, 1000 IU vitamin D plus 1000 mg evening primrose oil (Barij Essence, Kashan, Iran), daily, for 12 weeks orally. Control group: Placebo pearl (Barij Essence, Kashan, Iran), daily, for 12 weeks orally.

Main outcome variables

Outcomes: Lipid profiles (primary outcomes) and biomarkers of oxidative stress (secondary outcomes) will be measured at study baseline and after 12 weeks of intervention.

General information

Reason for update

The updating process was done after publishing the paper to correct the registration information.

Acronym

IRCT registration information

IRCT registration number: **IRCT201508025623N48**
Registration date: **2015-08-06, 1394/05/15**
Registration timing: **retrospective**

Last update: **2023-04-10, 1402/01/21**
Update count: **2**

Registration date

2015-08-06, 1394/05/15

Registrant information

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Zatollah Asemi
Name of organization / entity
Kashan University of Medical Sciences
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Recruitment status

Recruitment complete

Funding source

Arak University of Medical Sciences

Expected recruitment start date

2015-08-03, 1394/05/12

Expected recruitment end date

2015-08-06, 1394/05/15

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title
Clinical trial of the effect of combined vitamin D and evening primrose oil supplementation on metabolic profiles and oxidative stress 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:
Women aged 18-40 years diagnosed with PCOS

Exclusion criteria:
Elevated levels of prolactin Thyroid disorder Endocrine diseases including individuals with diabetes, impaired glucose tolerance Gastrointestinal diseases

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 supplements (n=30) or the standard diet (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
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
3848176941

Approval date
2015-08-02, 1394/05/11

Ethics committee reference number
IR.ARAKMU.REC.1394.92

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
Triglycerides

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

Method of measurement
Enzymatic kit

2

Description
HDL-cholesterol

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

Method of measurement
Enzymatic kit

3

Description
Total cholesterol

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

Method of measurement
Enzymatic kit

4

Description
LDL

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

intervention
Method of measurement
Enzymatic kit

5

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

Secondary outcomes

1

Description
Serum vitamin D
Timepoint
At the beginning of the study and after 12 weeks of intervention
Method of measurement
Elisa kit

2

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

3

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

4

Description
Glutathione
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
Modified Ferriman-Gallwey score
Timepoint
At the beginning of the study and after 12 weeks of intervention
Method of measurement
Questionnaire

7

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

Intervention groups

1

Description
Intervention group: Combined vitamin D and evening primrose oil pearl, 1000 IU vitamin D plus 1000 mg evening primrose oil, daily, for 12 weeks orally.
Category
Treatment - Drugs

2

Description
Control group: Placebo pearl, daily, for 12 weeks orally.
Category
Treatment - Drugs

Recruitment centers

1

Recruitment center
Name of recruitment center
Kosar outpatient Clinic
Full name of responsible person
Khadijeh Nasri
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Emam Khomeyni Avenue, Arak
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Sponsors / Funding sources

1

Sponsor
Name of organization / entity
Arak University of Medical Sciences
Full name of responsible person
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research@aums.ac.ir
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
Associate professor
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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