

# Clinical Trial Protocol

## Iranian Registry of Clinical Trials

13 Jun 2026

### Clinical trial of the effect of combined omega-3 and 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 combined omega-3 and vitamin D supplementation on metabolic and genetic 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, 60 patients will be selected according to inclusion and exclusion criteria.

##### Participants/Inclusion and exclusion criteria

Inclusion criteria: Patients with PCOS according to Rotterdam criteria, higher than 5 years of their disease and aged 18 to 40 years will be included in this study. Exclusion criteria: Pregnancy, adrenal hyperplasia, androgen secreting tumors, hyperprolactinemia, thyroid dysfunction, diabetes or impaired glucose tolerance.

##### Intervention groups

Intervention: Patients will be assigned into two groups to receive combined omega-3 and vitamin D (n=30) or placebo (n=30). Combined omega-3 and vitamin D, and placebo capsules are similar in shape and size.

##### Main outcome variables

Outcomes: Total testosterone (primary outcomes) and biomarkers of inflammation, oxidative stress, genetic and mental health (secondary outcome) will be quantified at study baseline and end-of-trial.

#### General information

##### Reason for update

##### Acronym

##### IRCT registration information

IRCT registration number: **IRCT201704245623N114**

Registration date: **2017-04-25, 1396/02/05**

Registration timing: **retrospective**

Last update: **2019-09-22, 1398/06/31**

Update count: **1**

##### Registration date

2017-04-25, 1396/02/05

##### 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

2017-02-21, 1395/12/03

##### Expected recruitment end date

2017-03-23, 1396/01/03

##### Actual recruitment start date

empty

##### Actual recruitment end date

empty

##### Trial completion date

empty

##### Scientific title

Clinical trial of the effect of combined omega-3 and 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 PCOS according to Rotterdam criteria Aged 18 to 40 years Written informed consent

**Exclusion criteria:**

Pregnancy Adrenal hyperplasia 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: **60**

**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**

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**

2017-02-20, 1395/12/02

**Ethics committee reference number**

IR.ARAKMU.REC.1395.406

**Health conditions studied****1****Description of health condition studied**

Polycystic ovarian 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

**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**

Malondialdehyde

**Timepoint**

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

**Method of measurement**

Spectrophotometry

**3****Description**

Glutathione

**Timepoint**

At the beginning of the study and after 12 weeks of

intervention

**Method of measurement**

Spectrophotometry

**4**

**Description**

Expressed levels of LL-1 gene

**Timepoint**

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

**Method of measurement**

PCR

**5**

**Description**

Expressed levels of TNF-a gene

**Timepoint**

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

**Method of measurement**

PCR

**6**

**Description**

Expressed levels of IL-8 gene

**Timepoint**

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

**Method of measurement**

PCR

**7**

**Description**

hs-CRP

**Timepoint**

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

**Method of measurement**

Elisa kit

**8**

**Description**

SHBG

**Timepoint**

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

**Method of measurement**

Elisa kit

**9**

**Description**

Beck score

**Timepoint**

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

**Method of measurement**

Questionnaire

**10**

**Description**

GHQ score

**Timepoint**

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

**Method of measurement**

Questionnaire

**11**

**Description**

DASS-28 score

**Timepoint**

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

**Method of measurement**

Questionnaire

**Intervention groups**

**1**

**Description**

Intervention group: 2000 mg omega-3 daily (Barij Essence, Kashan, Iran) and 50000 IU vitamin D every 2 weeks (Zahravi, Tabriz, Iran), for 12 weeks orally.

**Category**

Treatment - Drugs

**2**

**Description**

Control group: Placebo capsule (Barij Essence, Kashan, Iran), for 12 weeks orally.

**Category**

Placebo

**Recruitment centers**

**1**

**Recruitment center**

**Name of recruitment center**

Kosar Clinic

**Full name of responsible person**

Mehri Jamilian

**Street address**

Emam Khomeyni Avenue, Arak

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Markazi

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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

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Vice chancellor for research, Arak University of Medical Sciences, Sardasht Avenue, Arak

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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**

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

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**Fax****Email**

asemi\_z@kaums.ac.ir

**Web page address**

## Person responsible for scientific inquiries

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**Latest degree**

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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