

Clinical Trial Protocol

Iranian Registry of Clinical Trials

18 Sep 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 placebos 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		City Arak Province Markazi Postal code 3819693345 Approval date 2017-02-20, 1395/12/02 Ethics committee reference number IR.ARAKMU.REC.1395.406
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	Health conditions studied <u>1</u> Description of health condition studied Polycystic ovarian syndrome ICD-10 code E28.2 ICD-10 code description Polycystic ovarian syndrome	
		Primary outcomes <u>1</u> Description Total testosterone Timepoint At the beginning of the study and after 12 weeks of intervention Method of measurement Elisa kit
		Secondary outcomes <u>1</u> Description Total antioxidant Timepoint At the beginning of the study and after 12 weeks of intervention Method of measurement Spectrophotometry <u>2</u> Description Malondialdehyde Timepoint At the beginning of the study and after 12 weeks of intervention Method of measurement Spectrophotometry <u>3</u> Description Glutathione Timepoint At the beginning of the study and after 12 weeks of
Secondary Ids empty		
Ethics committees <u>1</u> 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		

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- α 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
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.i

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

8115187159

Phone

+98 31 5546 3378

Fax**Email**

asemi_z@kaums.ac.ir

Web page address

Person responsible for scientific inquiries

Contact**Name of organization / entity**

Kashan University of Medical Sciences

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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