

Clinical Trial Protocol

Iranian Registry of Clinical Trials

11 Jun 2026

Clinical trial of the effect of omega-3 fatty acids supplementation compared with the placebo on levels of gene expression related with glycemic control and inflammatory factors in women with polycystic ovary syndrome

Protocol summary

Summary

Objective: The aim of this study is to determine the effects of omega-3 fatty acids supplementation on levels of gene expression related with glycemic control and inflammatory factors in patients with polycystic ovary syndrome. 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. Inclusion criteria: Patients with polycystic ovary syndrome and aged 18 to 40 years will be included in this study. Exclusion criteria: Unwillingness to cooperate will be excluded in the study. Population and sample size: 60 patients with polycystic ovary syndrome of eligible and referred to Kosar Clinic affiliated to Arak University of Medical Sciences, Arak, Iran in the study will be selected. Intervention: Patients will be assigned to receive either omega-3 fatty acids (n=30) or placebo (n=30). Omega-3 fatty acids and placebos capsules are similar in shape and size. Fasting blood samples will be taken at baseline and 12 weeks after the intervention. At the beginning and end of the intervention: 12 weeks. Outcomes: Levels of gene expression related with glycemic control (primary outcomes) and inflammatory factors will be quantified at study baseline and end-of-trial.

General information

Acronym

IRCT registration information

IRCT registration number: **IRCT201606115623N83**

Registration date: **2016-06-15, 1395/03/26**

Registration timing: **retrospective**

Last update:

Update count: **0**

Registration date

2016-06-15, 1395/03/26

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

2016-04-23, 1395/02/04

Expected recruitment end date

2016-05-13, 1395/02/24

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Clinical trial of the effect of omega-3 fatty acids supplementation compared with the placebo on levels of gene expression related with glycemic control and inflammatory factors 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. Exclusion criteria: Unwillingness to cooperate.

Age

From **18 years** old to **40 years** old

Gender

Female

Phase

2

Groups that have been masked

No information

Sample size

Target sample size: **60**

Randomization (investigator's opinion)

Randomized

Randomization description**Blinding (investigator's opinion)**

Double blinded

Blinding description**Placebo**

Used

Assignment

Parallel

Other design features

Random assignment will be done by the use of computer-generated random numbers.

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

Postal code**Approval date**

2016-04-23, 1395/02/04

Ethics committee reference number

IR.ARAKMU.REC.1395.52

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**

Expressed levels of PPAR- γ

Timepoint

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

Method of measurement

PCR

2**Description**

Expressed levels of GLUT1 gene

Timepoint

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

Method of measurement

PCR

Secondary outcomes**1****Description**

Expressed levels of TNF α gene

Timepoint

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

Method of measurement

PCR

2**Description**

Expressed levels of IL-1 gene

Timepoint

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

Method of measurement

PCR

3**Description**

Expressed levels of IL-6 gene

Timepoint

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

Method of measurement

PCR

Intervention groups

1

Description

Intervention group: 1000 mg omega-3 fatty acids (Barij Essence, Kashan, Iran), twice a day, for 12 weeks orally.

Category

Treatment - Drugs

2

Description

Control group: Placebo (Barij Essence, Kashan, Iran), twice a day, 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

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

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

empty

Domestic or foreign origin

empty

Category of foreign source of funding

empty

Country of origin

Type of organization providing the funding

empty

Person responsible for general inquiries

Contact

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

Other areas of specialty/work

Street address

Ghotbe Ravandi Boulevard, Kashan

City

Kashan

Postal code

Phone

+98 31 5546 3378

Fax

Email

asemi_z@kaums.ac.ir; aseme_r@yahoo.com

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

Other areas of specialty/work

Street address

Ghotbe Ravandi Boulevard, Kashan

City

Kashan

Postal code

Phone

+98 31 5546 3378

Fax

Email

asemi_z@kaums.ac.ir; aseme_r@yahoo.com

Web page address

Sharing plan

Deidentified Individual Participant Data Set (IPD)

empty

Study Protocol

empty

Statistical Analysis Plan

empty
Informed Consent Form
empty
Clinical Study Report
empty

Analytic Code
empty
Data Dictionary
empty