Clinical Trial Protocol
Iranian Registry of Clinical Trials

09 Nov 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

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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

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 TNFα 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
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Person responsible for updating data

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Email
asemi_z@kaums.ac.ir; asemi_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