Clinical Trial Protocol
Iranian Registry of Clinical Trials

07 Nov 2026

Clinical trial of the effect of omega-3 plus vitamin E supplementation compared to placebo on level of gene expression related to glycemic control and inflammatory factors in women with polycystic ovary syndrome

Protocol summary

Study aim

Objective: The aim of this study is to determine the effects of omega-3 plus vitamin E supplementation on levels of gene expression related with glycemic control and inflammatory factors in patients with polycystic ovary syndrome.

Design

Study design: Parallel 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, 40 patients will be selected according to inclusion and exclusion criteria.

Participants/Inclusion and exclusion criteria

Inclusion criteria: Patients with PCOS according to Rotterdam criteria aged 18 to 40 years. Exclusion criteria: Smoking, intake of omega-3 fatty acids and/or vitamin E supplements within the last 3 months, intake of anti-inflammatory or antidiabetic drugs, pregnancy, other causes of hyperandrogenism and/or anovulation.

Intervention groups

Intervention group: Combined 1000 mg omega-3 fatty acids and 400 IU vitamin E, manufactured by Barij Essence, Kashan, Iran; once a day for 12 weeks, administered orally. Control group: Placebo manufactured by Barij Essence, Kashan, Iran; once a day for 12 weeks, administered orally.

Main outcome variables

Outcomes: Parameters of mental health (primary outcomes), levels of gene expression related with glycemic control and inflammatory factors (secondary outcomes) will be quantified at study baseline and end-of-trial.

General information

Reason for update

Due to an error, the request for an update in our website has conducted after paper published. However, the revisions were accordance with either the original approved proposal or with coordination with Vice Chancellor of Research at the University.

Acronym

IRCT registration information

IRCT registration number: **IRCT201605215623N79**
Registration date: **2016-05-25, 1395/03/05**
Registration timing: **retrospective**

Last update: **2019-11-25, 1398/09/04**
Update count: **1**

Registration date

2016-05-25, 1395/03/05

Registrant information

Name
Zatollah Asemi
Name of organization / entity
Kashan University of Medical Sciences
Country
Iran (Islamic Republic of)
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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

2016-03-08, 1394/12/18

Expected recruitment end date

2016-03-19, 1394/12/29

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Clinical trial of the effect of omega-3 plus vitamin E supplementation compared to placebo on level of gene expression related to 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:

Smoking Intake of omega-3 fatty acids and/or vitamin E supplements within the last 3 months Intake of anti-inflammatory or antidiabetic drugs Pregnancy Other causes of hyperandrogenism and/or anovulation

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: **40**

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 = 20) or placebo (n = 20). 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

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

Province

Markazi

Postal code

3819693345

Approval date

2016-03-07, 1394/12/17

Ethics committee reference number

IR.ARAKMU.REC.1394.335

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

Beck scor

Timepoint

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

Method of measurement

Questionnaire

2

Description

GHQ score

Timepoint

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

Method of measurement

Questionnaire

3

Description
DASS-28 score
Timepoint
At the beginning of the study and after 12 weeks of intervention
Method of measurement
Questionnaire

Secondary outcomes

1

Description
level of IL-1 gene expression
Timepoint
At the beginning of the study and after 12 weeks of intervention
Method of measurement
PCR

2

Description
level of IL-8 gene expression
Timepoint
At the beginning of the study and after 12 weeks of intervention
Method of measurement
PCR

3

Description
level of TNFα gene expression
Timepoint
At the beginning of the study and after 12 weeks of intervention
Method of measurement
PCR

4

Description
level of TGFB gene expression
Timepoint
At the beginning of the study and after 12 weeks of intervention
Method of measurement
PCR

5

Description
Gene expression of PPAR-gamma
Timepoint
At the beginning of the study and after 12 weeks of intervention
Method of measurement
PCR

6

Description
Gene expression of GLUT-1
Timepoint
At the beginning of the study and after 12 weeks of intervention
Method of measurement
PCR

Intervention groups

1

Description
Intervention group: Combined 1000 mg omega-3 fatty acids and 400 IU vitamin E, manufactured byBarij Essence, Kashan, Iran; once a day for 12 weeks, administered orally.
Category
Treatment - Drugs

2

Description
Control group: Placebo manufactured by Barij Essence, Kashan, Iran; once a day for 12 weeks, administered 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
Province
Markazi
Postal code
3819691187
Phone
+98 86 3313 6055
Email
jamilian.mehri@gmail.com

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

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3819693345

Phone

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Email

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

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

Associate professor

Latest degree

Ph.D.

Other areas of specialty/work

Nutrition

Street address

Ghotbe Ravandi Boulevard, Kashan

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8115187159

Phone

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Person responsible for scientific inquiries

Contact

Name of organization / entity

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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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Person responsible for updating data

Contact

Name of organization / entity

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Full name of responsible person

Zatollah Asemi

Position

PhD of Nutrition

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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