Clinical Trial Protocol
Iranian Registry of Clinical Trials

05 Jun 2026

The Effects of Omega-3 plus Vitamin E on Metabolic Syndrome Indicators And insulin resistance in Overweight Women with Polycystic Ovary Syndrome

Protocol summary

Study aim

The Effects of Omega-3 plus Vitamin E on Metabolic Syndrome Indicators And insulin resistance in Overweight Women with polycystic ovary syndrome (pcos)

Design

Sample size was assessed by a formula suggested for randomized clinical trials 2 gruop and each group 32 participants for Randomization use of Simple randomization . A written consent form was signed by all participants following an explanation of the study and its implementation process.

Settings and conduct

The patients were recruited from women referring to Isfahan Shahid Beheshti Hospital, in the city of Isfahan in Iran.

Participants/Inclusion and exclusion criteria

diabetes, hepatitis, non-alcoholic fatty liver, kidney diseases, thyroid disorders, cardiovascular diseases and Cushing's syndrome were excluded. oligo-ovulation or anovulation, the manifestation of hyper-androgenemia and the viewing of polycystic ovaries in ultrasound, the existence of two of which implicates the diagnosis of PCOS

Intervention groups

The participants were instructed to take two omega-3 pills (containing 180 mg eicosapentaenoic acid(EPA) and 120 mg docosahexaenoic acid(DHA)) and a pearl vitamin E (400 IU) or placebos (liquid paraffin) every day for 8 weeks

Main outcome variables

reduction in the values of TG, FBS, total Cholesterol, LDL-C, systolic blood pressure (SBP), diastolic blood pressure (DBP) and insulin serum concentration, and significantly enhances HDL-C levels

General information

Reason for update

Acronym

pcos

IRCT registration information

IRCT registration number: **IRCT20200812048379N1**
Registration date: **2020-10-26, 1399/08/05**
Registration timing: **retrospective**

Last update: **2020-10-26, 1399/08/05**
Update count: **0**

Registration date

2020-10-26, 1399/08/05

Registrant information

Name

Fateme Sadeghi

Name of organization / entity

Country

Iran (Islamic Republic of)

Phone

+98 31 3788 3449

Email address

minasadeghi294@yahoo.com

Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2018-04-21, 1397/02/01

Expected recruitment end date

2018-07-23, 1397/05/01

Actual recruitment start date

2018-05-08, 1397/02/18

Actual recruitment end date

2018-10-12, 1397/07/20

Trial completion date

2018-12-31, 1397/10/10

Scientific title
The Effects of Omega-3 plus Vitamin E on Metabolic Syndrome Indicators And insulin resistance in Overweight Women with Polycystic Ovary Syndrome

Public title
The Effects of Omega-3 plus Vitamin E on Metabolic Syndrome Indicators And insulin resistance in Overweight Women with Polycystic Ovary Syndrome

Purpose
Treatment

Inclusion/Exclusion criteria

Inclusion criteria:
oligo-ovulation or anovulation the manifestation of hyper-androgenemia or symptom of hyperandrogenism the viewing of polycystic ovaries in ultrasound

Exclusion criteria:
cardiovascullar deases kidney diseases diabetes Cushing's syndrome were hepatitis non-alcoholic fatty liver thyroid disorders

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

Gender
Female

Phase
3

Groups that have been masked

- Participant
- Investigator

Sample size
Target sample size: **64**
Actual sample size reached: **64**

Randomization (investigator's opinion)
Randomized

Randomization description
After selecting the participants for the study, we assigned the participants to the study groups using Random Allocation software. Since we had two groups in this study, we specified the number of participants and the number of groups in the software. In addition, we will choose a simple randomization method. Entered the study was also based on software output. In this study, the physician who selected patients based on inclusion and non-inclusion criteria was not aware of the software output and only after selecting the project manager based on the patient's choice and based on the software output assigned each intervention.

Blinding (investigator's opinion)
Double blinded

Blinding description
Subjects were randomly divided in to two groups of A and B by computer and zero and one digits of Simple randomization . Researchers and subjects didn't know which groups take supplement or placebo until the end of the study.

Placebo
Used

Assignment
Parallel

Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee
Ethics committee of Esfahan University of Medical Sciences

Street address
Isfahan University Of Medical Sciences ;Isfahan, Iran

City
اصفهان

Province
Isfehan

Postal code
۷۳۴۶۱-۸۱۷۴۶

Approval date
2016-09-20, 1395/06/30

Ethics committee reference number
IR.MUI.REC.1395.3.407

Health conditions studied

1

Description of health condition studied
Polycystic ovary syndrome

ICD-10 code

ICD-10 code description

Primary outcomes

1

Description
FBS

Timepoint
beginning study befor of using supplement and the end of the study after completion supplement.

Method of measurement
10cc of venous blood was collected before and after the trial and after measuring with special kits.

2

Description
Triglyceride

Timepoint
beginning study befor of using supplement and the end of the study after completion supplement.

Method of measurement
10cc of venous blood was collected before and after the trial and after measuring with special kits.

3

Description
Low density lipoproteien
Timepoint
beginning study befor of using supplement and the end of the study after completion supplement.
Method of measurement
10cc of venous blood was collected before and after the trial and after measuring with special kits.

4

Description
Fasting insulin
Timepoint
beginning study befor of using supplement and the end of the study after completion supplement.
Method of measurement
10cc of venous blood was collected before and after the trial and after measuring with special kits.

5

Description
Ligh density lipoproteien
Timepoint
beginning study befor of using supplement and the end of the study after completion supplement.
Method of measurement
10cc of venous blood was collected before and after the trial and after measuring with special kits.

6

Description
Waist cicumfrance
Timepoint
beginning study befor of using supplement and the end of the study after completion supplement.
Method of measurement
was measured in standing position from the lowest rib to the extremity of the pelvic bone fracture using an anthropometric meter.

7

Description
systolic blood pressure
Timepoint
beginning study befor of using supplement and the end of the study after completion supplement.
Method of measurement
after 5 minut of rest with mercury barometer

8

Description
diastolic blood pressure
Timepoint
beginning study befor of using supplement and the end of the study after completion supplement.
Method of measurement
after 5 minut of rest with mercury barometer.

Secondary outcomes

empty

Intervention groups

1

Description
Intervention group: every day 2 capsul 1000mg Omega 3 and one 400 IU vitamin E of DANA factory for 60 days.
Category
Treatment - Drugs

2

Description
Control group:every day 2 plasebo of omega 3 and one plasebo of vitamin E same of intervention group.
Category
Treatment - Drugs

Recruitment centers

1

Recruitment center
Name of recruitment center
Isfahan Shahid Beheshti Hospital
Full name of responsible person
Fateme sadeghi
Street address
Shahid Beheshti Avenue
City
اصفهان
Province
Isfehan
Postal code
8178634514
Phone
+98 31 3668 1378
Email
am.alavi@nutr.mui.ac.ir

Sponsors / Funding sources

1

Sponsor
Name of organization / entity
Esfahan University of Medical Sciences
Full name of responsible person
Amir mansur alavi
Street address
Hezar jarib Avenue
City
اصفهان
Province
Isfehan
Postal code
8174673461
Phone

+98 31 3668 1378

Email

am.alavi@nutr.mui.ac.ir

Grant name

Grant code / Reference number

Is the source of funding the same sponsor organization/entity?

Yes

Title of funding source

Esfahan 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

Esfahan University of Medical Sciences

Full name of responsible person

Amir mansur alavi

Position

Professor

Latest degree

Ph.D.

Other areas of specialty/work

Nutrition

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Person responsible for scientific inquiries

Contact

Name of organization / entity

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Full name of responsible person

Amir mansur alavi

Position

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Latest degree

Ph.D.

Other areas of specialty/work

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Person responsible for updating data

Contact

Name of organization / entity

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Full name of responsible person

Amir mansur alavi

Position

professor

Latest degree

Ph.D.

Other areas of specialty/work

Nutrition

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Sharing plan

Deidentified Individual Participant Data Set (IPD)

No - There is not a plan to make this available

Justification/reason for indecision/not sharing IPD

test pattern

Study Protocol

No - There is not a plan to make this available

Statistical Analysis Plan

No - There is not a plan to make this available

Informed Consent Form

No - There is not a plan to make this available

Clinical Study Report

No - There is not a plan to make this available

Analytic Code

No - There is not a plan to make this available

Data Dictionary

No - There is not a plan to make this available