Clinical Trial Protocol
Iranian Registry of Clinical Trials

07 Nov 2026

Effect of omega-3 fatty acids supplementation on serum levels of malondialdehyde, total antioxidant capacity and paraoxonase1 in polycystic ovary syndrome patients

Protocol summary

Summary

This study was a randomized single-blind placebo controlled trial on 60 women with polycystic ovary syndrome. Total purpose of this study was to determine the effect of omega-3 fatty acids supplementation on malondialdehyde, total antioxidant capacity and paraxonase 1 in polycystic ovary syndrome patients and the practical purpose of the study was to help to prevent and treatment of PCOS and the complications of this disease such as diabetes and cardiovascular disease. Inclusion criteria were woman with polycystic ovary syndrome who had 20-35 years old and Body Mass Index=25-40; Exclusion criteria were Thyroid disorders; hyperprolactinemia; cushing syndrome; liver, kidney and cardiovascular disease; diabetes; pregnancy and lactation; smoking; use of anti obesity drugs; lipid lowering agent; glucocorticids; anti coagulation drugs; use a lowering weight diet; have a usual sports program; receiving omega-3 supplement during 2 month ago and receiving any nutritional supplements during the study. A general questionnaire (including age, weight, height, Body Mass Index,...) and 3 days food record completed for each subjects at the beginning of the study. Then the subjects were randomly assigned to intervention and control group. Fasting venous blood sample obtained from each patients at the beginning of the study and biochemical parameters like malondialdehyde, total antioxidant capacity and paraoxonase1 measured. Patients in intervention group took 2 omega-3 capsules with 1gr weight (containing 360 mg EPA and 240 mg DHA) for 2 month and control group took 2 capsules containing sunflower oil for 2 month. The participants advised to keep their diet and physical activity with no changes. At the end of the study the anthropometric measurements and food intake evaluated again and blood sampling obtained again for measuring biochemical parameters.

General information

Acronym

IRCT registration information

IRCT registration number: **IRCT201106243664N5**
Registration date: **2011-07-18, 1390/04/27**
Registration timing: **retrospective**

Last update:
Update count: **0**

Registration date

2011-07-18, 1390/04/27

Registrant information

Name

Maryam Rafraf

Name of organization / entity

Tabriz University Of Medical Sciences

Country

Iran (Islamic Republic of)

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Recruitment status

Recruitment complete

Funding source

Vice-chancellor for Research, Tabriz University of Medical Science

Expected recruitment start date

2010-11-22, 1389/09/01

Expected recruitment end date

2011-01-21, 1389/11/01

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date
empty

Scientific title
Effect of omega-3 fatty acids supplementation on serum levels of malondialdehyde, total antioxidant capacity and paraoxonase1 in polycystic ovary syndrome patients

Public title
Effect of omega-3 fatty acids supplementation on serum levels of malondialdehyde, total antioxidant capacity and paraoxonase1 in polycystic ovary syndrome patients

Purpose
Supportive

Inclusion/Exclusion criteria
Inclusion criteria:woman with polycystic ovary syndrome; 20-35 years old and BMI=25-40; Exclusion criteria: Thyroid disorders; hyperprolactinemia; cushing syndrome; liver,kidney and cardiovascular disease; diabetes; pregnancy and lactation; smoking; use of anti obesity drugs; lipid lowering agent; glucocorticids; anti coagulation drugs; use a lowering weight diet; have a usual sports program; receiving omega-3 supplement during 2 month ago and receiving any nutritional supplements during the study.

Age
From **20 years** old to **35 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)
Single blinded

Blinding description

Placebo
Used

Assignment
Parallel

Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee
Ethics Committee of Tabriz University of Medical Science

Street address
Tabriz University of Medical Science, Attar Neishabouri Avenue, Golgasht street, Tabriz

City
Tabriz

Postal code

Approval date
2010-12-13, 1389/09/22

Ethics committee reference number
5/4/7663

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
Malondialdehyde(MDA)

Timepoint
baseline and at the end of intervention

Method of measurement
Fluorimetry method

Secondary outcomes

1

Description
Total antioxidant capacity

Timepoint
baseline and at the end of intervention

Method of measurement
FRAP

2

Description
paraxonase1(PON1)

Timepoint
baseline and at the end of intervention

Method of measurement
Spectrophotometry

Intervention groups

1

Description
Intervention group: 2 capsules of omega-3 containing 360 mg EPA and 240 mg DHA for 2 months

Category
Other

2

Description
Control group: 2 placebo capsules containing sunflower oil for 2 months
Category
Placebo

Recruitment centers

1

Recruitment center
Name of recruitment center
Alzahra clinic
Full name of responsible person
Elahe Mohammadi
Street address
Health and nutrition school, Attar Neishabouri Avenue, Golgasht street, Tabriz
City
Tabriz

Sponsors / Funding sources

1

Sponsor
Name of organization / entity
Nutritional Research Center,Tabriz University of Medical Sciences
Full name of responsible person
Dr Alireza Ostadrahimi
Street address
Health and nutrition school, Attar Neishabouri Avenue, Golgasht street
City
Tabriz
Grant name
Grant code / Reference number
Is the source of funding the same sponsor organization/entity?
Yes
Title of funding source
Nutritional Research Center,Tabriz 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
Name of organization / entity
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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