

Clinical Trial Protocol

Iranian Registry of Clinical Trials

02 Jun 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 paraoxonase 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; glucocorticoids; 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 Rafram

Name of organization / entity

Tabriz University Of Medical Sciences

Country

Iran (Islamic Republic of)

Phone

+98 41 1335 7580

Email address

rafram@tbzmed.ac.ir

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; glucocorticoids; 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

Tabriz University of Medical science

Full name of responsible person

Elahe Mohammadi

Position

MS student in Nutrition

Other areas of specialty/work

Street address

Health and Nutrition School, Attar Neishabouri Avenue, Golgasht street, Tabriz

City

Tabriz

Postal code

Phone

+98 41 1335 7580

Fax

Email

e.mohamadi52@yahoo.com

Web page address

Person responsible for scientific inquiries

Contact

Name of organization / entity

Tabriz University of Medical science

Full name of responsible person

Elahe Mohammadi

Position

MS student in Nutrition

Other areas of specialty/work

Street address

Health and Nutrition School, Attar Neishabouri Avenue, Golgasht street, Tabriz

City

Tabriz

Postal code

Phone

+98 41 1335 7580

Fax

Email

e.mohamadi52@yahoo.com

Web page address

Person responsible for updating data

Contact

Name of organization / entity

Tabriz University of Medical Science

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Street address

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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