

# 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

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**Email**

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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*