

# Clinical Trial Protocol

## Iranian Registry of Clinical Trials

09 Jul 2026

### Effect of omega-3 fatty acids supplementation on metabolic status, serum levels of high-sensitivity of C-reactive protein, adiponectin and visfatin in polycystic ovary syndrome patients

#### Protocol summary

##### Summary

This study is a randomized double-blind placebo controlled trial on 64 women with polycystic ovary syndrome. A general questionnaire (including age, weight, height, body mass index) and 3-day, 24-hour dietary recalls will be completed for each subject at the beginning of the study. Then the subjects will be randomly assigned to intervention and control group. Fasting venous blood sample(10 cc) will be obtained from each patient at the beginning of the study and biochemical parameters like blood glucose, insulin level, triglyceride concentration, total cholesterol, LDL and HDL cholesterol, hs-CRP (High-sensitivity of C-reactive protein), adiponectin and visfatin will be measured. Patients in intervention group will take 4 omega-3 capsules (containing 180 mg eicosapentaenoic acid and 120 mg docosahexaenoic acid) for 2 month and control group will take placebo capsules containing paraffin oil for 2 month. The participants should keep their diet and physical activity with no changes. At the end of the study the anthropometric measurements and food intake will be evaluated again and blood sampling will be obtained again for measuring biochemical parameters

#### General information

##### Acronym

##### IRCT registration information

IRCT registration number: **IRCT201011083664N3**  
Registration date: **2011-02-03, 1389/11/14**  
Registration timing: **retrospective**

Last update:

Update count: **0**

##### Registration date

2011-02-03, 1389/11/14

#### Registrant information

##### Name

Maryam Rafraf

##### Name of organization / entity

Tabriz University Of Medical Sciences

##### Country

Iran (Islamic Republic of)

##### Phone

+98 41 1335 7580

##### Email address

rafrafm@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 metabolic status, serum levels of high-sensitivity of C-reactive protein, adiponectin and visfatin in polycystic ovary syndrome patients

#### Public title

Effect of omega-3 fatty acids supplementation in polycystic ovary syndrome patients

#### Purpose

Supportive

## Inclusion/Exclusion criteria

Inclusion criteria: woman with polycystic ovary syndrome, 20-35 years old and BMI of 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: **64**

## Randomization (investigator's opinion)

Randomized

## Randomization description

## Blinding (investigator's opinion)

Double blinded

## Blinding description

## Placebo

Used

## Assignment

Parallel

## Other design features

## Secondary Ids

empty

## Ethics committees

### 1

#### Ethics committee

##### Name of ethics committee

The Research Ethics Committee of Tabriz University of Medical Sciences

##### Street address

Attar neishaboori Avenue, Golgasht Atreet

##### City

Tabriz

##### Postal code

#### Approval date

2010-12-23, 1389/10/02

#### 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

fasting blood glucose

#### Timepoint

baseline and at the end of intervention

#### Method of measurement

enzymatic method

## Secondary outcomes

### 1

#### Description

fasting serum insulin level and insulin resistance

#### Timepoint

baseline and at the end of intervention

#### Method of measurement

Elisa method and HOMA-IR formula

### 2

#### Description

lipid profile(TG,LDL,HDL,Total cholesterol)

#### Timepoint

baseline and at the end of intervention

#### Method of measurement

Enzymatic method with special kits for assessing TG,HDL and total cholesterol and friedewald equation for assessing LDL cholesterol

### 3

#### Description

hs-CRP

#### Timepoint

baseline and at the end of intervention

#### Method of measurement

immunoturbidometric method

### 4

#### Description

adiponectin

#### Timepoint

baseline and at the end of intervention

#### Method of measurement

Elisa method

### 5

#### Description

visfatin

#### Timepoint

baseline and at the end of intervention

**Method of measurement**

Elisa method

**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 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

**City**

Tabriz

**Sponsors / Funding sources****1****Sponsor****Name of organization / entity**

Vice-chancellor for research, Tabriz University of Medical Sciences

**Full name of responsible person**

Maryam Rafraf

**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**

Vice-chancellor for research, 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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**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*