Clinical Trial Protocol
Iranian Registry of Clinical Trials

17 Sep 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 (containig 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

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Name of organization / entity
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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 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
immunotorbidometric 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
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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