Clinical Trial Protocol
Iranian Registry of Clinical Trials

04 Jun 2026

The effects of fish oil supplementation on hormonal profiles and oxidative stress parameters in patients with polycystic ovary syndrome

Protocol summary

Study aim

The effects of fish oil supplementation on hormonal profiles and oxidative stress parameters in patients with polycystic ovary syndrome

Design

In this research, 60 patients with polycystic ovary syndrome who are eligible will be selected. Participants are randomly divided into two groups of intervention and control by computer software. The design of the study is parallel blind randomized clinical trial.

Settings and conduct

60 patients with polycystic ovary syndrome who are eligible and are referred to women sections of Naghavii hospital affiliated to Kashan University of Medical Sciences, Kashan, Iran will be selected. The design of the study is a double blind randomized clinical tria. Blinding is carried out for patients and researchers and randomization is done by random table numbers. Patients will be assigned to receive either fish oil (intervention group: n=30) or placebo (control group: n=30). Fasting blood samples will be taken at baseline and after 12 week intervention

Participants/Inclusion and exclusion criteria

Inclusion Criteria: Women with polycystic ovary syndrome aged 18 to 35 years, on the basis of Rotterdam criteria and without smoking abuse will be included in this study. Exclusion Criteria: Patients who do not want to cooperate; patients with polycystic ovary syndrome with revealed diabetes, hypo or hyperthyroidism, hyperprolactinemia are excluded from this study.

Intervention groups

Patients will be assigned to receive either fish oil (intervention group: n=30) or placebo (control group: n=30).

Main outcome variables

serum levels of total testosterone, Free testosterone, DHEA sulfate, SHBG, oxidative stress factors such as malondialdehyde (MDA), glutathione (GSH), total antioxidant capacity will be measured.

General information

Reason for update

The updating process was done after publishing the paper to correct the registration information.

Acronym

IRCT registration information

IRCT registration number: **IRCT20150606022562N4**
Registration date: **2018-02-17, 1396/11/28**
Registration timing: **retrospective**

Last update: **2023-04-22, 1402/02/02**
Update count: **1**

Registration date

2018-02-17, 1396/11/28

Registrant information

Name

Fereshteh Bahmani

Name of organization / entity

Kashan University of Medical Sciences

Country

Iran (Islamic Republic of)

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Recruitment status

Recruitment complete

Funding source

Vice chancellor for research, Kashan University of Medical Sciences

Expected recruitment start date

2017-12-01, 1396/09/10

Expected recruitment end date

2017-12-31, 1396/10/10

Actual recruitment start date
empty
Actual recruitment end date
empty
Trial completion date
empty

Scientific title
The effects of fish oil supplementation on hormonal profiles and oxidative stress parameters in patients with polycystic ovary syndrome

Public title
The effect of fish oil in patients with polycystic ovary syndrome
Purpose
Treatment
Inclusion/Exclusion criteria
Inclusion criteria:
Women aged 18-35 Polycystic ovary syndrome on the basis of Rotterdam criteria No smoking
Exclusion criteria:
Revealed diabetes Hypothyroidism or hyperthyroidism Hyperprolactinemia Cushing's syndrome and adrenal and ovarian tumors Unwillingness to continue cooperation No regular use of the prescribed supplement
Age
From **18 years** old to **35 years** old
Gender
Female

Phase
2
Groups that have been masked

- Participant
- Care provider
- Investigator
- Outcome assessor
- Data analyser

Sample size
Target sample size: **60**
Randomization (investigator's opinion)
Randomized
Randomization description
The method of randomization is that women with PCOS are based on two criteria: BMI (25BMI <and 25BMI≥) and age (30 and 30 ≤) in the stratification they take. The method of randomization with a simple method and the use of random numbers generated by computer software will be performed.
Blinding (investigator's opinion)
Double blinded
Blinding description
In this study, participants, researchers, data collectors, evaluators and data analyzers are not aware of which group of placebo and supplemented fish oil groups.
Placebo
Used
Assignment
Parallel
Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee
Name of ethics committee
Ethics Committee of Kashan university of medical sciences and health services
Street address
Kashan University of Medical Sciences, Ravand road
City
Kashan
Province
Isfehan
Postal code
8715988141
Approval date
2017-10-19, 1396/07/27
Ethics committee reference number
IR.KAUMS.MEDNT.REC.1396.25

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
Total Testosterone
Timepoint
At the beginning of the study and 12 weeks after intervention
Method of measurement
ELISA kit

2

Description
SHBG
Timepoint
At the beginning of the study and 12 weeks after intervention
Method of measurement
ELISA kit

3

Description
Serum insulin

Timepoint
At the beginning of the study and 12 weeks after intervention
Method of measurement
Elisa kit

4

Description
Insulin resistance
Timepoint
At the beginning of the study and 12 weeks after intervention
Method of measurement
Calculated with suggested formula

5

Description
Insulin sensitivity
Timepoint
At the beginning of the study and 12 weeks after intervention
Method of measurement
Calculated with suggested formula

Secondary outcomes

1

Description
Total Gluthatione
Timepoint
At the beginning of the study and 12 weeks after intervention
Method of measurement
In plasma sample will assessed by cholorimetric method. µmol/L

2

Description
plasma total antioxidant
Timepoint
At the beginning of the study and 12 weeks after intervention
Method of measurement
In plasma sample will assessed by cholorimetric method. µmol/L

3

Description
Malondialdehyde (MAD)
Timepoint
At the beginning of the study and 12 weeks after intervention
Method of measurement
In plasma sample will assessed by cholorimetric method. µmol/L

4

Description
High-sensitivity C-reactive protein
Timepoint
At the beginning of the study and 12 weeks after intervention
Method of measurement
Elisa kit

5

Description
Nitric oxide
Timepoint
At the beginning of the study and 12 weeks after intervention
Method of measurement
In plasma sample will assessed by cholorimetric method. µmol/L

6

Description
Beck score
Timepoint
At the beginning of the study and after 12 weeks of intervention
Method of measurement
Questionnaire

7

Description
GHQ score
Timepoint
At the beginning of the study and after 12 weeks of intervention
Method of measurement
Questionnaire

8

Description
DASS-28 score
Timepoint
At the beginning of the study and after 12 weeks of intervention
Method of measurement
Questionnaire

9

Description
Modified Ferriman Gallwey
Timepoint
At the beginning of the study and after 12 weeks of intervention
Method of measurement
Questionnaire

10

Description

Triglycerides

Timepoint

At the beginning of the study and after 12 weeks of intervention

Method of measurement

Enzymatic kit

11

Description

VLDL-cholesterol

Timepoint

At the beginning of the study and after 12 weeks of intervention

Method of measurement

Enzymatic kit

12

Description

Total cholesterol

Timepoint

At the beginning of the study and after 12 weeks of intervention

Method of measurement

Enzymatic kit

13

Description

LDL-cholesterol

Timepoint

At the beginning of the study and after 12 weeks of intervention

Method of measurement

Enzymatic kit

14

Description

HDL-cholesterol

Timepoint

At the beginning of the study and after 12 weeks of intervention

Method of measurement

Enzymatic kit

15

Description

Fasting plasma glucose

Timepoint

At the beginning of the study and after 12 weeks of intervention

Method of measurement

Enzymatic kit

Intervention groups

1

Description

Intervention: received two capsules of 1gr fish oil daily for 12 weeks

Category

Treatment - Other

2

Description

control: received two capsules of placebo daily for 12 weeks

Category

Placebo

Recruitment centers

1

Recruitment center

Name of recruitment center

Women's Clinic of Naghavi Hospital

Full name of responsible person

Dr. Fatemeh Forouzan Fard

Street address

Naghavi Hospital, Ayatollah Kashai Ave

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Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Kashan University of Medical Sciences

Full name of responsible person

Dr. Gholam Ali Hamidi

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Vice chancellor for research, Kashan University of Medical Sciences ,Ravand road

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hamidi_gh@kaums.ac.ir

Grant name

Grant code / Reference number

Is the source of funding the same sponsor organization/entity?

Yes

Title of funding source

Kashan University of Medical Sciences

Proportion provided by this source

100

Public or private sector

Public

Domestic or foreign origin

Domestic

Category of foreign source of funding

empty

Country of origin

Type of organization providing the funding

Academic

Person responsible for general inquiries

Contact

Name of organization / entity

Kashan University of Medical Sciences

Full name of responsible person

Fereshteh Bahmani

Position

Associate Professor/ Academic staff member of the Department of Clinical Biochemistry

Latest degree

Ph.D.

Other areas of specialty/work

Clinical Biochemistry

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Web page address

Sharing plan

Deidentified Individual Participant Data Set (IPD)

Undecided - It is not yet known if there will be a plan to make this available

Study Protocol

Undecided - It is not yet known if there will be a plan to make this available

Statistical Analysis Plan

Undecided - It is not yet known if there will be a plan to make this available

Informed Consent Form

Undecided - It is not yet known if there will be a plan to make this available

Clinical Study Report

Undecided - It is not yet known if there will be a plan to make this available

Analytic Code

Undecided - It is not yet known if there will be a plan to make this available

Data Dictionary	Undecided - It is not yet known if there will be a plan to make this available