

# 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 trial. 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)

##### Phone

+98 31 5554 0021

##### Email address

fbahmani@kaums.ac.ir

##### 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 ( $25\text{BMI} <$  and  $25\text{BMI} \geq$ ) and age ( $30 >$  and  $30 \leq$ ) 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**

Isfahan

**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 colorimetric method.  $\mu\text{mol/L}$

**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 colorimetric method.  $\mu\text{mol/L}$

**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 colorimetric method.  $\mu\text{mol/L}$

**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 colorimetric method.  $\mu\text{mol/L}$

**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

**City**

Kashan

**Province**

Isfahan

**Postal code**

8715988141

**Phone**

+98 31 5554 0021

**Email**

fbahmani@kaums.ac.ir

**Sponsors / Funding sources**

**1**

**Sponsor**

**Name of organization / entity**

Kashan University of Medical Sciences

**Full name of responsible person**

Dr. Gholam Ali Hamidi

**Street address**

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

**City**

Kashan

**Province**

Isfahan

**Postal code**

8715988141

**Phone**

+98 31 5554 2999

**Email**

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  
**Street address**  
Medical Faculty, Kashan University of Medical  
Sciences, Ravand road  
**City**  
Kashan  
**Province**  
Isfahan  
**Postal code**  
8715988141  
**Phone**  
+98 31 5554 0021  
**Fax**  
**Email**  
bahmani@kaums.ac.ir  
**Web page address**

## Person responsible for scientific 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  
**Street address**  
Medical Faculty, Kashan University of Medical  
Sciences, Ravand road  
**City**

Kashan  
**Province**  
Isfahan  
**Postal code**  
8715988141  
**Phone**  
+98 31 5554 0021  
**Fax**  
**Email**  
fbahmani@kaums.ac.ir  
**Web page address**

## Person responsible for updating data

### 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  
**Street address**  
Medical Faculty, Kashan University of Medical  
Sciences, Ravand road  
**City**  
Kashan  
**Province**  
Isfahan  
**Postal code**  
8715988141  
**Phone**  
+98 31 5554 0021  
**Fax**  
**Email**  
fbahmani@kaums.ac.ir  
**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