

# Clinical Trial Protocol

## Iranian Registry of Clinical Trials

13 Jun 2026

### Clinical trial of the effect of fish oil supplementation compared with the placebo on levels of gene expression related with glycemic control and inflammatory factors in women with polycystic ovary syndrome

#### Protocol summary

##### Study aim

Objective: The aim of this study is to determine the effects of fish oil supplementation on levels of gene expression related with glycemic control and inflammatory factors in patients with polycystic ovary syndrome.

##### Design

Study design: Parallel double-blind (both patients and researchers) clinical trial. Randomization will be done by the use of computer-generated random numbers.

##### Settings and conduct

Population and sample size: 40 patients with polycystic ovary syndrome of eligible and referred to Persian Gulf Martyrs Hospital affiliated to Bushehr University of Medical Sciences, Bushehr, Iran and Kosar affiliated to Arak University of Medical Sciences, Arak, Iran in the study will be selected.

##### Participants/Inclusion and exclusion criteria

Inclusion criteria: Patients with PCOS according to Rotterdam criteria aged 18 to 40 years. Exclusion criteria: Pregnant women, diabetes and impaired glucose tolerance, hypo or hyperthyroidism, androgen-secreting tumor, or hyperprolactinemia.

##### Intervention groups

Patients will be assigned to receive either fish oil (n=20) or placebo (n=20). Fish oil and placebo capsules are similar in shape and size.

##### Main outcome variables

Outcomes: Levels of gene expression related with glycemic control (primary outcomes) and inflammatory factors will be quantified at study baseline and end-of-trial.

#### General information

##### Reason for update

Unfortunately, due to carelessness, update request was

done after publishing paper. In addition, the requested issues are in accordance with the approved proposal or with the coordination of Vice Chancellor of Research of University.

##### Acronym

##### IRCT registration information

IRCT registration number: **IRCT201609305623N89**

Registration date: **2016-10-01, 1395/07/10**

Registration timing: **retrospective**

Last update: **2019-10-18, 1398/07/26**

Update count: **1**

##### Registration date

2016-10-01, 1395/07/10

##### Registrant information

##### Name

Zatollah Asemi

##### Name of organization / entity

Kashan University of Medical Sciences

##### Country

Iran (Islamic Republic of)

##### Phone

+98 36 1534 3570

##### Email address

asemi\_z@kaums.ac.ir

##### Recruitment status

**Recruitment complete**

##### Funding source

Vice chancellor of research, Bushehr University of Medical Sciences

##### Expected recruitment start date

2016-09-24, 1395/07/03

##### Expected recruitment end date

2016-10-01, 1395/07/10

##### Actual recruitment start date

empty

**Actual recruitment end date**

empty

**Trial completion date**

empty

**Scientific title**

Clinical trial of the effect of fish oil supplementation compared with the placebo on levels of gene expression related with glycemic control and inflammatory factors in women with polycystic ovary syndrome

**Public title**

Effect of supplementation in treatment of women with polycystic ovary syndrome

**Purpose**

Treatment

**Inclusion/Exclusion criteria****Inclusion criteria:**

Patients with PCOS according to Rotterdam criteria aged 18 to 40 years

**Exclusion criteria:**

Pregnant women Diabetes and impaired glucose tolerance Hypo or hyperthyroidism Androgen-secreting tumor Hyperprolactinemia

**Age**

From **18 years** old to **40 years** old

**Gender**

Female

**Phase**

3

**Groups that have been masked**

- Participant
- Investigator
- Outcome assessor

**Sample size**

Target sample size: **40**

**Randomization (investigator's opinion)**

Randomized

**Randomization description**

At study baseline, after balanced blocked randomisation, subjects will be allocated into two groups to take supplements (n=20) or placebo (n=20). Randomization will be done by the use of computer-generated random numbers.

**Blinding (investigator's opinion)**

Double blinded

**Blinding description**

Participants, investigators or the assessors of the outcomes are unaware of the study groups.

**Placebo**

Used

**Assignment**

Parallel

**Other design features****Secondary Ids**

empty

**Ethics committees****1****Ethics committee****Name of ethics committee**

Ethics committee of Bushehr University of Medical Sciences

**Street address**

Bahmani Campus, Bushehr University of Medical Sciences, Sabzabad Blvd

**City**

Bushehr

**Province**

Boushehr

**Postal code**

7518759577

**Approval date**

2016-09-24, 1395/07/03

**Ethics committee reference number**

IR.BPUMS.REC.1395.86

**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**

PPAR-γ

**Timepoint**

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

**Method of measurement**

PCR

**2****Description**

GLUT-1

**Timepoint**

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

**Method of measurement**

PCR

**Secondary outcomes****1****Description**

Interleukin 8

**Timepoint**

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

**Method of measurement**

PCR

**2****Description**

Tumor necrosis factor alpha

**Timepoint**

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

**Method of measurement**

PCR

**3****Description**

Interleukin 1

**Timepoint**

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

**Method of measurement**

PCR

**4****Description**

LDLR

**Timepoint**

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

**Method of measurement**

PCR

**5****Description**

Lp(a)

**Timepoint**

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

**Method of measurement**

PCR

**6****Description**

TGF- $\beta$

**Timepoint**

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

**Method of measurement**

PCR

**Intervention groups****1****Description**

Intervention group: 1000 mg fish oil (Barij Essence, Kashan, Iran), twice a day, for 12 weeks orally.

**Category**

Treatment - Drugs

**2****Description**

Control group: Placebo (Barij Essence, Kashan, Iran), twice a day, for 12 weeks orally.

**Category**

Treatment - Drugs

**Recruitment centers****1****Recruitment center****Name of recruitment center**

Persian Gulf Martyrs Hospital

**Full name of responsible person**

Dr Elham Rahmani

**Street address**

Persian Gulf Martyrs Hospital, Borj square, Borj Blvd

**City**

Bushehr

**Province**

Boushehr

**Postal code**

7518759577

**Phone**

+98 77 3345 0089

**Email**

rahmani-e@bums.ac.ir

**2****Recruitment center****Name of recruitment center**

Kosar Clinic

**Full name of responsible person**

Mehri Jamilian

**Street address**

Emam Khomeyni Avenue, Arak

**City**

Arak

**Province**

Markazi

**Postal code**

3814113634

**Phone**

+98 86 3223 3823

**Email**

jamilian.mehri@gmail.com

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

Vice chancellor of research, Bushehr University of Medical Sciences

**Full name of responsible person**

Dr Afshin Ostovar

**Street address**

Bahmani Campus, University of Medical Sciences,  
Sabzabad Blvd

**City**

Bushehr

**Province**

Boushehr

**Postal code**

7514633341

**Phone**

+98 77 3345 0089

**Email**

research@bums.ac.ir

**Grant name**

**Grant code / Reference number**

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

Yes

**Title of funding source**

Vice chancellor of research, Bushehr 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**

Zatollah Asemi

**Position**

Associate professor

**Latest degree**

Ph.D.

**Other areas of specialty/work**

Nutrition

**Street address**

Ghotbe Ravandi Boulevard, Kashan

**City**

Kashan

**Province**

Isfahan

**Postal code**

81151-87159

**Phone**

+98 31 5546 3378

**Email**

asemi\_r@yahoo.com

## Person responsible for scientific inquiries

**Contact**

**Name of organization / entity**

Kashan University of Medical Sciences

**Full name of responsible person**

Zatollah Asemi

**Position**

PhD of Nutrition

**Latest degree**

Ph.D.

**Other areas of specialty/work**

Nutrition

**Street address**

Ghotbe Ravandi Boulevard, Kashan

**City**

Kashan

**Province**

Isfahan

**Postal code**

81151-87159

**Phone**

+98 31 5546 3378

**Fax**

**Email**

asemi\_r@yahoo.com

**Web page address**

## Person responsible for updating data

**Contact**

**Name of organization / entity**

Kashan University of Medical Sciences

**Full name of responsible person**

Zatollah Asemi

**Position**

PhD of Nutrition

**Latest degree**

Ph.D.

**Other areas of specialty/work**

Nutrition

**Street address**

Ghotbe Ravandi Boulevard, Kashan

**City**

Kashan

**Province**

Isfahan

**Postal code**

81151-87159

**Phone**

+98 31 5546 3378

**Fax**

**Email**

asemi\_r@yahoo.com

**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