Clinical Trial Protocol
Iranian Registry of Clinical Trials

09 Nov 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 placebos 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
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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-β
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
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Bushehr
Province
Boushehr
Postal code
7518759577
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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
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Arak
Province
Markazi
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3814113634
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+98 86 3223 3823
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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

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7514633341

Phone
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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

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PhD of Nutrition

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Person responsible for updating data

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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