

# Clinical Trial Protocol

## Iranian Registry of Clinical Trials

06 Jun 2026

### Effect of Omega3 supplementation on Visfatin, Adiponectin, and Anthropometric indices in women with polycystic ovary syndrome

#### Protocol summary

##### Summary

Aim of this study: Effect of Omega3 supplementation on Visfatin, Adiponectin, and Anthropometric indices in women with polycystic ovary syndrome. This study is Randomized, double-blind, controlled with placebo, single-center, second phase of trial. Method: The study will be conducted on 64 women with polycystic ovary syndrome (20-40y) with a BMI 25-40, refer to Reproductive Science Institute and Shahid Sadoughi hospital. The exclusion criteria is Diabetes and Hypothyroid. After checking the inclusion criteria, and filling the consent form, they will be divided into 2 groups randomly. One group will take capsules of Omega-3 (3 g/d) and control group take placebos for 2 months. Type of the study is Randomized Double Blind Placebo-controlled Clinical Trial. Inclusion criteria: females 20-40 years; PCOS diagnostic according to Rotterdam criteria; BMI > 25; No history about intake of any drug during the last 3 months that may affect the insulin sensitivity or hormonal profile such as: oral contraceptives, glucocorticoids, ovulation induction agents, anti-diabetic and anti-obesity drugs, estrogenic, antiandrogenic or anti-hypertensive medication. Not being in any diet in the last 3 months. Do not have any addiction to tobacco and alcohol; Do not take an Omega-3 supplement in the last 3 months; Do not be menopause; Do not use anti-coagulant medicine or anti-depression medication; Do not be diabetic and hypothyroidism. Exclusion criteria: Essentially needs for intake of OCP to treatment; Do not obey the Protocols of the study and do not ingest more than 20% of supplements. Blood samples (adiponectin, visfatin, LH, FSH, prolactin) and Anthropometric indices are measured before and after intervention.

#### General information

##### Acronym

PCOS, LH, FSH

#### IRCT registration information

IRCT registration number: **IRCT2012071410281N1**

Registration date: **2012-09-09, 1391/06/19**

Registration timing: **retrospective**

Last update:

Update count: **0**

#### Registration date

2012-09-09, 1391/06/19

#### Registrant information

##### Name

Hoorieh Daneshbodi

##### Name of organization / entity

Shahid Sadoughi University of Medical Sciences and Health Services

##### Country

Iran (Islamic Republic of)

##### Phone

+98 21 2207 9836

##### Email address

h\_daneshbodi@ssu.ac.ir

#### Recruitment status

**Recruitment complete**

#### Funding source

Institute for Reproductive Sciences, Research and Clinical Center for Infertility, Shahid Sadoughi University of Medical Sciences and Health Services

#### Expected recruitment start date

2012-06-21, 1391/04/01

#### Expected recruitment end date

2012-08-22, 1391/06/01

#### Actual recruitment start date

empty

#### Actual recruitment end date

empty

#### Trial completion date

empty

**Scientific title**

Effect of Omega3 supplementation on Visfatin, Adiponectin, and Anthropometric indices in women with polycystic ovary syndrome

**Public title**

Effect of Omega 3 supplementation in women with polycystic ovary syndrome

**Purpose**

Supportive

**Inclusion/Exclusion criteria**

criteria inclusion: females 20-40years; PCOS diagnostic according to Rotterdam criteria; BMI>25; No history about intake of any drug during the last 3 months that may affect the insulin sensitivity or hormonal profile such as: oral contraceptives, glucocorticoids, ovulation induction agents, anti diabetic and anti obesity drugs, estrogenic, antiandrogenic or anti hypertensive medication; Not being in any diet in the last 3month; Do not have any addiction to tobacco and alcohol; Do not taking a Omega-3 supplement in the last 3 month; Do not be menopause; Do not use anti-coagulant medicine; Do not use anti-depression medication; Do not be diabetic and hypothyroidism. exclusion criteria: Essentially needs for intake of OCP to treatment; Do not will to be in the study; Do not obey the Protocols of the study and do not digest more than 20% of supplements.

**Age**

From **20 years** old to **40 years** old

**Gender**

Female

**Phase**

N/A

**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**

Shahid sadoughi university of medical sciences and health servicesInstitute for Reproductive Scienc

**Street address**

yazd-Safaeeye-Bouali avenue,infertility research center.

**City**

yazd

**Postal code**

8916877391

**Approval date**

2011-10-23, 1390/08/01

**Ethics committee reference number**

2162

**Health conditions studied****1****Description of health condition studied**

polycystic ovary syndrome

**ICD-10 code**

E28.2

**ICD-10 code description**

Sclerocystic ovary syndrome Stein-Leventhal syndrome

**Primary outcomes****1****Description**

serum visfatin-

**Timepoint**

before and after intervention

**Method of measurement**

visfatin ng/ml Elisa kit-

**2****Description**

serum adiponectin

**Timepoint**

before and after intervention

**Method of measurement**

adiponectin Elisa kit µg/ml-

**3****Description**

serum LH

**Timepoint**

before and after intervention

**Method of measurement**

LH Elisa kit U/l

**4****Description**

serum FSH

**Timepoint**

before and after intervention

**Method of measurement**

FSH Elisa kit U/l-

## 5

### Description

serum Prolactin

### Timepoint

before and after intervention

### Method of measurement

prolactin Elisa ng/mL

## 6

### Description

body weight

### Timepoint

before and after intervention

### Method of measurement

leveled platform scale

## 7

### Description

BMI-

### Timepoint

before and after intervention

### Method of measurement

leveled platform scale-stadiometer

## 8

### Description

waist circumference

### Timepoint

before and after intervention

### Method of measurement

tape

## 9

### Description

hip circumference

### Timepoint

before and after intervention

### Method of measurement

tape

## Secondary outcomes

empty

## Intervention groups

### 1

#### Description

intervention: capsules of fish-oil (3 g/d) for 2 month

#### Category

Placebo

### 2

#### Description

placebos of fish-oil (3 g/d) for 2 month

#### Category

Placebo

## Recruitment centers

### 1

#### Recruitment center

##### Name of recruitment center

Institute for Reproductive Sciences, Research and clinical Center for Infertility

##### Full name of responsible person

Hoorieh Daneshbodi

##### Street address

yazd-Safaeeye-Bouali avenue, Institute for Reproductive Sciences, Research and clinical Center for Infertility

##### City

yazd

### 2

#### Recruitment center

##### Name of recruitment center

shahid sadoughi hospital

##### Full name of responsible person

Hoorieh Daneshbodi

##### Street address

Atlasi square-shahid ghandi Boulevard-ebne sina street

##### City

yazd

## Sponsors / Funding sources

### 1

#### Sponsor

##### Name of organization / entity

Institute for Reproductive Sciences, Research and clinical Center for Infertility

##### Full name of responsible person

Dr Ali Mohammad Abdoli

##### Street address

yazd-Safaeeye-Bouali avenue-Institute for Reproductive Sciences, Research and clinical Center for Infertility

##### City

yazd

##### Grant name

151450

##### Grant code / Reference number

151450

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

Yes

##### Title of funding source

Institute for Reproductive Sciences, Research and clinical Center for Infertility

##### 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**

Shahid sadoughi university of medical sciences and health services

**Full name of responsible person**

Hoorieh Daneshbodi

**Position**

-Executive-Ms,c student in nutrition and health science

**Other areas of specialty/work****Street address**

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**Person responsible for updating data****Contact****Name of organization / entity**

Shahid sadoughi university of medical sciences and health services

**Full name of responsible person**

Hoorieh Daneshbodi

**Position**

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**Other areas of specialty/work****Street address****City****Postal code****Phone**

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**Web page address****Person responsible for scientific inquiries****Contact****Name of organization / entity**

Shahid sadoughi university of medical sciences and health services-health college

**Full name of responsible person**

Dr Azadeh Najarzadeh

**Position**

Assistant Professor

**Other areas of specialty/work****Street address**

Daneshjoo Blv-Shahid sadoughi university of medical sciences and health services-health college

**City****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*