

# Clinical Trial Protocol

## Iranian Registry of Clinical Trials

30 May 2026

### Clinical and metabolic response to herbal and animal omega-3 fatty acids supplementation in women with poly cystic ovary syndrome

#### Protocol summary

##### Summary

Objective: the aim of this study is to determine the effects of herbal and animal omega-3 fatty acid supplementation on hormonal and metabolic profiles in patients with polycystic ovary syndrome (PCOS). Study design: parallel double-blind (both patients and researchers) randomized controlled clinical trial. Inclusion criteria: patients with PCOS according to Rotterdam criteria, higher than 5 years of their disease and aged 18 to 40 years will be included in this study. Exclusion criteria: unwillingness to cooperate will be excluded in the study. Population and sample size: 105 patients with PCOS of eligible and referred to Naghavi Clinic affiliated to Kashan University of Medical Sciences, Kashan, Iran in the study will be selected. Intervention: patients will be assigned to receive herbal omega-3 fatty acid (flax seed oil)(intervention group: n=35) and animal omega-3 supplements (intervention group: n=35) or placebo (control group: n=35). Start and end date of intervention: 12 weeks. Outcomes: hormonal and metabolic profiles will be measured at study baseline and end-of-trial.

#### General information

##### Acronym

##### IRCT registration information

IRCT registration number: **IRCT2016041612438N19**  
Registration date: **2016-05-05, 1395/02/16**  
Registration timing: **registered\_while\_recruiting**

Last update:

Update count: **0**

##### Registration date

2016-05-05, 1395/02/16

##### Registrant information

Name

Mohsen Taghizadeh

##### Name of organization / entity

Kashan University of Medical Sciences

##### Country

Iran (Islamic Republic of)

##### Phone

+98 36 1555 0021

##### Email address

taghizadeh\_m@kaums.ac.ir

##### Recruitment status

**Recruitment complete**

##### Funding source

Barij Research Center of Medicinal Herbs

##### Expected recruitment start date

2016-04-20, 1395/02/01

##### Expected recruitment end date

2016-10-22, 1395/08/01

##### Actual recruitment start date

empty

##### Actual recruitment end date

empty

##### Trial completion date

empty

##### Scientific title

Clinical and metabolic response to herbal and animal omega-3 fatty acids supplementation in women with poly cystic ovary syndrome

##### Public title

The effect of herbal and animal omega-3 fatty acids on polycystic ovary syndrome

##### Purpose

Treatment

##### Inclusion/Exclusion criteria

Inclusion criteria: patients with PCOS according to Rotterdam criteria; higher than 5 years of their disease; aged 18 to 40 years. Exclusion criterion: unwillingness to cooperate.

##### Age

From **18 years** old to **40 years** old  
**Gender**  
Female  
**Phase**  
2-3  
**Groups that have been masked**  
*No information*  
**Sample size**  
Target sample size: **105**  
**Randomization (investigator's opinion)**  
Randomized  
**Randomization description**  
**Blinding (investigator's opinion)**  
Double blinded  
**Blinding description**  
**Placebo**  
Used  
**Assignment**  
Parallel  
**Other design features**  
Randomized based on table of random numbers

## Secondary Ids

empty

## Ethics committees

### 1

#### Ethics committee

**Name of ethics committee**  
Ethics committee of Kashan University of Medical Sciences  
**Street address**  
Kashan University Of Medical Sciences, Kashan  
**City**  
Kashan  
**Postal code**  
**Approval date**  
2016-03-04, 1394/12/14  
**Ethics committee reference number**  
IR.KAUMS.REC.1394.175

## Health conditions studied

### 1

**Description of health condition studied**  
Polycystic ovarian syndrome  
**ICD-10 code**  
E28.2  
**ICD-10 code description**  
Polycystic ovarian syndrome

## Primary outcomes

### 1

**Description**  
Hirsutism

**Timepoint**  
Baseline and End-of-trial  
**Method of measurement**  
Observation

### 2

**Description**  
Insulin resistance  
**Timepoint**  
Baseline and End-of-trial  
**Method of measurement**  
Blood sample

### 3

**Description**  
Insulin  
**Timepoint**  
Baseline and End-of-trial  
**Method of measurement**  
Blood sample

### 4

**Description**  
Testosterone  
**Timepoint**  
Baseline and End-of-trial  
**Method of measurement**  
Blood sample

### 5

**Description**  
Prolactin  
**Timepoint**  
Baseline and End-of-trial  
**Method of measurement**  
Blood sample

### 6

**Description**  
Follicular- stimulating hormone  
**Timepoint**  
Baseline and End-of-trial  
**Method of measurement**  
Blood sample

### 7

**Description**  
Acne  
**Timepoint**  
Baseline and End-of-trial  
**Method of measurement**  
Observation

### 8

**Description**  
Lipid profile  
**Timepoint**

Baseline and End-of-trial  
**Method of measurement**  
Blood sample

9

**Description**

Hair loss

**Timepoint**

Baseline and End-of-trial

**Method of measurement**

Observation

10

**Description**

DHEAs

**Timepoint**

Baseline and End-of-trial

**Method of measurement**

Blood sample

**Secondary outcomes**

empty

**Intervention groups**

1

**Description**

Intervention group 1: Herbal Omega-3 fatty acid capsule,2 times per day for 12 weeks orally.

**Category**

Treatment - Drugs

2

**Description**

Intervention group 2: Fish oil Omega-3 fatty acid capsule,2 times per day for 12 weeks orally.

**Category**

Treatment - Drugs

3

**Description**

Control group:placebo capsule,2 times per day for 12 weeks orally.

**Category**

Placebo

**Recruitment centers**

1

**Recruitment center**

**Name of recruitment center**

Naghavi Clinic

**Full name of responsible person**

Zatollah Asemi

**Street address**

**City**

Kashan

**Sponsors / Funding sources**

1

**Sponsor**

**Name of organization / entity**

Barij Research Center of Medicinal Herbs

**Full name of responsible person**

Miss Laleh Hejazi

**Street address**

Kashan Mashhad Ardehal Road, KM44

**City**

Kashan

**Grant name**

**Grant code / Reference number**

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

Yes

**Title of funding source**

Barij Research Center of Medicinal Herbs

**Proportion provided by this source**

**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

2

**Sponsor**

**Name of organization / entity**

Vice chancellor for research of Kashan University of Medical Science

**Full name of responsible person**

Dr. Gholam Ali Hamidi

**Street address**

Kashan university of Medical Science, Kashan

**City**

Kashan

**Grant name**

**Grant code / Reference number**

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

Yes

**Title of funding source**

Vice chancellor for research of Kashan University of Medical Science

**Proportion provided by this source**

**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**

Kashan University of Medical Sciences

**Full name of responsible person**

Dr. Mohsen Taghizadeh

**Position**

PhD

**Other areas of specialty/work**

**Street address**

Kashan University of Medical Sciences, Kashan

**City**

Kashan

**Postal code**

**Phone**

+98 31 5554 0021

**Fax**

**Email**

mohsenta44@yahoo.com

**Web page address**

## Person responsible for scientific inquiries

### Contact

**Name of organization / entity**

Kashan University of Medical Sciences

**Full name of responsible person**

Dr. Mohsen Taghizadeh

**Position**

PhD

**Other areas of specialty/work**

**Street address**

Kashan University of Medical Sciences, Kashan

**City**

Kashan

**Postal code**

**Phone**

+98 31 5554 0021

**Fax**

**Email**

mohsenta44@yahoo.com

**Web page address**

## Person responsible for updating data

### Contact

**Name of organization / entity**

Barij Research Center of Medicinal Herbs

**Full name of responsible person**

Mahnaz Mahlouji

**Position**

Clinical Expert

**Other areas of specialty/work**

**Street address**

Km44 of Kashan - Delijan Rd., Mashhad-e- Ardehal

Kashan

**City**

Kashan

**Postal code**

**Phone**

+98 86 4446 5112

**Fax**

**Email**

mahnaz.mahlouji@yahoo.com

**Web page address**

## 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*