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 measeaured 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 efffect 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