

Clinical Trial Protocol

Iranian Registry of Clinical Trials

05 Jun 2026

Clinical trial of the effect of combined omega-3 fatty acid and vitamin E supplementation compared with the placebo on hormonal profiles in women with polycystic ovary syndrome

Protocol summary

Study aim

Objective: The aim of this study is to determine the effects of combined omega-3 fatty acid and vitamin E supplementation on hormonal profiles in patients with polycystic ovary syndrome (PCOS).

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: 64 women with PCOS eligible and referred to Naghavi Clinic affiliated to Kashan University of Medical Sciences, Kashan, 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, uncontrolled hypertension, hypo or hyperthyroidism, liver disease, androgen-secreting tumor, or hyperprolactinemia.

Intervention groups

Intervention group: Combined 1000 mg omega-3 fatty acids and 400 IU vitamin E, manufactured by Barij Essence, Kashan, Iran; once a day for 12 weeks, administered orally. Control group: Placebo manufactured by Barij Essence, Kashan, Iran; once a day for 12 weeks, administered orally.

Main outcome variables

Outcomes: Markers of insulin metabolism (primary outcomes) and hormonal parameters and other metabolic profiles (secondary outcomes).

General information

Reason for update

Due to an error, the request for an update in our website was conducted after paper published. However, the

revisions were accordance with either the original approved proposal or with coordination with Vice Chancellor of Research at the University.

Acronym

IRCT registration information

IRCT registration number: **IRCT201511015623N57**

Registration date: **2015-11-03, 1394/08/12**

Registration timing: **registered_while_recruiting**

Last update: **2019-10-31, 1398/08/09**

Update count: **1**

Registration date

2015-11-03, 1394/08/12

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

Kashan University of Medical Sciences

Expected recruitment start date

2015-11-01, 1394/08/10

Expected recruitment end date

2015-11-11, 1394/08/20

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Clinical trial of the effect of combined omega-3 fatty acid and vitamin E supplementation compared with the placebo on hormonal profiles 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 Uncontrolled hypertension Hypo or hyperthyroidism Liver disease 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: **64**

Randomization (investigator's opinion)

Randomized

Randomization description

At study baseline and after stratification for pre-intervention BMI and age, subjects will be randomly divided into two groups to take supplements (n=32) or placebo (n=32). 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 Kashan University of Medical Sciences

Street address

Kashan University of Medical Sciences

City

Kashan

Province

Isfahan

Postal code

8715988141

Approval date

2015-10-28, 1394/08/06

Ethics committee reference number

IR.Kaums.REC.1394.90

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**

Insulin resistance

Timepoint

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

Method of measurement

Calculation using HOMA formula

2**Description**

Insulin

Timepoint

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

Method of measurement

Elisa kit

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

Testosterone

Timepoint

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

Method of measurement

Elisa kit

2

Description

SHBG

Timepoint

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

Method of measurement

Elisa kit

3

Description

DHEAS

Timepoint

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

Method of measurement

Elisa kit

4

Description

FPG

Timepoint

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

Method of measurement

Enzymatic kit

5

Description

Hirsutism

Timepoint

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

Method of measurement

Clinical observation

Intervention groups

1

Description

Control group: Placebo capsule, daily for 12 weeks orally.

Category

Treatment - Drugs

2

Description

Intervention group: Omega-3 fatty acid and vitamin E capsule, 1000 mg omega-3 fatty acid and 400 mg vitamin E, daily for 12 weeks orally.

Category

Treatment - Drugs

Recruitment centers

1

Recruitment center

Name of recruitment center

Naghavi Clinic

Full name of responsible person

Zatollah Asemi

Street address

Shahid Rajaei Avenue, Kashan

City

Kashan

Province

Isfahan

Postal code

8715988141

Phone

+98 31 5546 3378

Email

asemi_r@yahoo.com

Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Vice chancellor for research, Kashan University of Medical Sciences

Full name of responsible person

Gholamali Hamidi

Street address

Kashan University of Medical Sciences

City

Kashan

Province

Isfahan

Postal code

8115187159

Phone

+98 31 5554 0022

Email

research@kaums.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 for research, Kashan 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

8715988141

Phone

+98 913 361 5447

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

8715988141

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

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PhD of Nutrition

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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