Clinical Trial Protocol
Iranian Registry of Clinical Trials

18 Sep 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
Isfehan
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 Rajaee Avenue, Kashan
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Isfehan
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8715988141
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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
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Kashan University of Medical Sciences
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8115187159
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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

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Position
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