Clinical Trial Protocol
Iranian Registry of Clinical Trials

10 Jun 2026

Clinical trial of the effect of carnitine supplementation compared with the placebo on carotid intima-media thickness and biomarkers of inflammation in women with polycystic ovary syndrome

Protocol summary

Study aim
The aim of this study is to determine the effects of carnitine supplementation on carotid intima-media thickness (CIMT) and biomarkers of inflammation in women with polycystic ovary syndrome.

Design
Parallel double-blind (both patients and researchers) clinical trial

Settings and conduct
Among patients with polycystic ovary syndrome referred to Naghavi Clinic affiliated to Kashan University of Medical Sciences, 60 patients will be selected according to inclusion and exclusion criteria.

Participants/Inclusion and exclusion criteria
Patients with polycystic ovary syndrome aged 18 to 40 years will be included in this study. Exclusion criteria will as follows: Pregnant women, elevated levels of prolactin, and endocrine diseases.

Intervention groups
Patients will be assigned to receive either carnitine (n=30) or placebo (n=30).

Main outcome variables
Carotid intima-media thickness (primary outcome) and biomarkers of inflammation (secondary outcomes)

General information

Reason for update

Acronym

IRCT registration information
IRCT registration number: **IRCT2017070433941N3**
Registration date: **2017-07-31, 1396/05/09**
Registration timing: **retrospective**

Last update: **2019-09-24, 1398/07/02**
Update count: **1**

Registration date
2017-07-31, 1396/05/09

Registrant information

Name
Mohammadreza Sharif

Name of organization / entity

Country
Iran (Islamic Republic of)

Phone
+98 31 5546 3378

Email address
ostadmohammadi-vr@kaums.ac.ir

Recruitment status
Recruitment complete

Funding source
Vice chancellor for research, Kashan University of Medical Sciences

Expected recruitment start date
2016-07-11, 1395/04/21

Expected recruitment end date
2016-08-11, 1395/05/21

Actual recruitment start date
empty

Actual recruitment end date
empty

Trial completion date
empty

Scientific title
Clinical trial of the effect of carnitine supplementation compared with the placebo on carotid intima-media thickness and biomarkers of inflammation in women with polycystic ovary syndrome

Public title
Effect of carnitine supplementation in treatment of women with polycystic ovary syndrome

Purpose

Treatment

Inclusion/Exclusion criteria

Inclusion criteria:

Patients with polycystic ovary syndrome according to Rotterdam criteria Aged 18 to 40 years

Exclusion criteria:

Pregnant women Elevated levels of prolactin Endocrine diseases

Age

From **18 years** old to **40 years** old

Gender

Female

Phase

N/A

Groups that have been masked

- Participant
- Investigator
- Outcome assessor

Sample size

Target sample size: **60**

Randomization (investigator's opinion)

Randomized

Randomization description

At study baseline and after balanced blocked randomization, subjects will be randomly divided into two groups to take either carnitine supplements (n = 30) or placebo (n =30). Randomization will be done by the use of computer-generated random numbers.

Blinding (investigator's opinion)

Double blinded

Blinding description

Randomization and allocation will be concealed from the researchers and participants until the final analyses are completed. Another person at the Naghavi Clinic, who is not involved in the trial and not aware of random sequences, will be assigned the participants to the numbered bottles of capsules.

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

Ghotbe Ravandi Boulevard, Kashan

City

Kashan

Province

Isfehan

Postal code

8715988141

Approval date

2016-07-10, 1395/04/20

Ethics committee reference number

IR.KAUMS.REC.1395.21

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

Mean left CIMT

Timepoint

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

Method of measurement

Sonography

2

Description

Maximum left CIMT

Timepoint

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

Method of measurement

Sonography

3

Description

Mean right CIMT

Timepoint

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

Method of measurement

Sonography

4

Description

Maximum right CIMT

Timepoint

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

Method of measurement

Sonography

Secondary outcomes

1

Description
Hs-CRP
Timepoint
At the beginning of the study and after 12 weeks of intervention
Method of measurement
Elisa kit

2

Description
Nitric oxide
Timepoint
At the beginning of the study and after 12 weeks of intervention
Method of measurement
Spectrophotometry

Intervention groups

1

Description
Intervention group: 250 mg carnitine (Avecina, Tehran, Iran), once a day, for 12 weeks orally.
Category
Treatment - Drugs

2

Description
Control group: Placebo (Barij Essence, Kashan, Iran), once a day, 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
City
Kashan
Province
Isfehan
Postal code
8715988141
Phone
+98 31 5546 3378
Email
asemi_r@yahoo.com

Sponsors / Funding sources

1

Sponsor
Name of organization / entity
Kashan University of Medical Sciences
Full name of responsible person
Gholamali Hamidi
Street address
Ghotbe Ravandi Boulevard, Kashan
City
Kashan
Province
Isfehan
Postal code
81151-87159
Phone
+98 31 5554 2999
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
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
Ph.D of Nutrition
Latest degree
Ph.D.
Other areas of specialty/work
Nutrition
Street address
Ghotbe Ravandi Boulevard, Kashan
City
Kashan
Province
Isfehan
Postal code
81151-87159
Phone

+98 36 1534 3570

Fax

Email

asemi_z@kaums.ac.ir

Web page address

Person responsible for scientific inquiries

Contact

Name of organization / entity

Kashan University of Medical Sciences

Full name of responsible person

Zatollah Asemi

Position

Ph.D of Nutrition

Latest degree

Ph.D.

Other areas of specialty/work

Nutrition

Street address

Ghotbe Ravandi Boulevard, Kashan

City

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Province

Isfehan

Postal code

81151-87159

Phone

+98 31 5546 3378

Fax

Email

asemi_z@kaums.ac.ir

Web page address

Person responsible for updating data

Contact

Name of organization / entity

Kashan University of Medical Sciences

Full name of responsible person

وحید رضا استاد محمدی

Position

Student

Latest degree

Medical doctor

Other areas of specialty/work

General Practitioner

Street address

Ghotbe Ravandi Boulevard, Kashan

City

Kashan

Province

Isfehan

Postal code

81151-87159

Phone

+98 31 5556 0608

Email

ostadmohammadi-vr@kaums.ac.ir

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