

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

2017-07-31, 1396/05/09

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 be 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

Registrant information

Name

Mohammadreza Sharif

Name of organization / entity

Country

Iran (Islamic Republic of)

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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

Isfahan
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 Rajaei Avenue, Kashan

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Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Kashan University of Medical Sciences

Full name of responsible person

Gholamali Hamidi

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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

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General Practitioner

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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