

Clinical Trial Protocol

Iranian Registry of Clinical Trials

11 Jul 2026

Comparison of the effect of oral L-carnitine and placebo supplementation on anthropometric indices, lipid status, insulin and hormone resistance indices in obese / overweight women suffering from polycystic ovary syndrome

Protocol summary

Study aim

To evaluate the effect of weight loss regimen with and without L- carnitine supplementation on lipids, insulin and hormone resistance indices in women in reproductive age with polycystic ovary syndrome and overweight/obesity.

Design

A randomized, double blinded, controlled clinical trial with a sample size of 62 patients. Enrollment will be done between October 2019 and January 2020

Settings and conduct

The study was conducted at Yazd Diabetes Center. In order to do blinding, drugs were packed in separate envelopes without informing patients and researchers.

Participants/Inclusion and exclusion criteria

Inclusion criteria: 18-45 year-old women referred to Kashan Naghavi Hospital; Polycystic Ovarian Syndrome based on Rotterdam Diagnostic Criteria; Body Mass Index 25 and over; Interested to participate in study. Non-inclusion criteria: smoking; diabetes or thyroid disease; people who have been on a special diet for the past three months or have used a weight-loss drug, hormone, and ovulation stimulant.

Intervention groups

The intervention group should take a daily dose of 1000 mg carnitine capsules with lunch and the placebo group should use capsules which are exactly as same as carnitine capsules in the shape and color but without any active ingredient. Both groups will use the capsules for 12 weeks.

Main outcome variables

Fasting blood sugar; insulin; HOMA and SHBG index; triglyceride; cholesterol; HDL; LDL

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20191016045131N1**

Registration date: **2019-12-30, 1398/10/09**

Registration timing: **registered_while_recruiting**

Last update: **2019-12-30, 1398/10/09**

Update count: **0**

Registration date

2019-12-30, 1398/10/09

Registrant information

Name

Fatemeh Pakravanfar

Name of organization / entity

Country

Iran (Islamic Republic of)

Phone

+98 31 5557 3812

Email address

fatemeh.p1993@yahoo.com

Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2019-10-21, 1398/07/29

Expected recruitment end date

2020-01-19, 1398/10/29

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Comparison of the effect of oral L-carnitine and placebo supplementation on anthropometric indices, lipid status, insulin and hormone resistance indices in obese / overweight women suffering from polycystic ovary syndrome

Public title

The effect of oral L-carnitine supplementation on polycystic ovary syndrome

Purpose

Treatment

Inclusion/Exclusion criteria

Inclusion criteria:

18-45 years old women referred to Yazd Diabetes Center Polycystic ovary syndrome based on Rotterdam diagnostic criteria Body Mass Index 25 and over interested in participation in the study Taking usual treatment of PCOS

Exclusion criteria:

Smoking Suffering from diabetes or thyroid disease Having a special diet for the past three months Weight-loss medication, hormone or ovulation stimulant use

Age

From **18 years** old to **45 years** old

Gender

Female

Phase

3

Groups that have been masked

- Participant
- Care provider
- Investigator
- Outcome assessor
- Data analyser

Sample size

Target sample size: **62**

Randomization (investigator's opinion)

Randomized

Randomization description

Random allocation tables

Blinding (investigator's opinion)

Double blinded

Blinding description

Blinding the researcher and participants. For this purpose the tablets were initially packaged in two packages A and B. The nature of the tablets will remain hidden from the participants and researchers until after the study.

Placebo

Used

Assignment

Parallel

Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee

Ethics committee of Yazd University of Medical Sciences

Street address

Central Building of Shahid Sadoughi University of Medical Sciences, Bahonar Square

City

Yazd

Province

Yazd

Postal code

8715113514

Approval date

2018-05-22, 1397/03/01

Ethics committee reference number

IR.SSU.SPH.REC.1397.014

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

Insulin

Timepoint

At the beginning and at the end of the study (120 days later)

Method of measurement

Insulin Kit

2

Description

fasting blood sugar

Timepoint

At the beginning and at the end of the study (120 days later)

Method of measurement

Blood test

3

Description

Sex hormone-binding globulin

Timepoint

At the beginning and at the end of the study (120 days later)

Method of measurement

kit

4**Description**

triglyceride

Timepoint

At the beginning and at the end of the study (120 days after)

Method of measurement

Blood test

5**Description**

Cholesterol

Timepoint

At the beginning and at the end of the study (120 days later)

Method of measurement

Blood test

6**Description**

HDL

Timepoint

At the beginning and at the end of the study (120 days later)

Method of measurement

Blood test

7**Description**

LDL

Timepoint

At the beginning and at the end of the study (120 days later)

Method of measurement

Blood test

8**Description**

HOMA IR

Timepoint

At the beginning and at the end of the study (120 days later)

Method of measurement

By formula using fasting glucose and insulin

Secondary outcomes

empty

Intervention groups**1****Description**

Control group: receiving placebo containing non-active

substance for 12 weeks

Category

Placebo

2**Description**

Intervention group: Oral administration of L-carnitine supplement 1000 mg daily for 12 weeks

Category

Treatment - Drugs

Recruitment centers**1****Recruitment center****Name of recruitment center**

Yazd Diabetes Research Center

Full name of responsible person

Dr.Nasim Namiranian

Street address

At the end of Talare Honar Alley, Shahid Sadoughi Boulevard, from Bahonar Square to Azadi Square

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diabet_center@yahoo.com

Sponsors / Funding sources**1****Sponsor****Name of organization / entity**

Yazd University of Medical Sciences

Full name of responsible person

Mohammad Hassan Ehrampoosh

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School of Public Health, Shahid Sadoughi University of Medical Sciences, Shohadaye Gomnam Boulevard, Alam Square, Yazd

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ravabet.odb@ssu.ac.ir

Grant name**Grant code / Reference number****Is the source of funding the same sponsor organization/entity?**

Yes

Title of funding source

Yazd 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

Yazd University of Medical Sciences

Full name of responsible person

Fatemeh Pakravanfar

Position

University student

Latest degree

Bachelor

Other areas of specialty/work

Nutrition

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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

Not applicable

Data Dictionary

Not applicable