Clinical Trial Protocol
Iranian Registry of Clinical Trials

22 Nov 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
City
Yazd
Province
Yazd
Postal code
8715113514
Phone
+98 35 3728 0226
Email
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
Street address
School of Public Health, Shahid Sadoughi University of Medical Sciences, Shohadaye Gomnam Boulevard, Alam Square, Yazd
City
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Province
Yazd
Postal code
۸۹۱۵۱۷۳۱۶۰
Phone
+98 35 3820 9100
Email
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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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

Not applicable

Data Dictionary

Not applicable