Clinical Trial Protocol
Iranian Registry of Clinical Trials

04 Jun 2026

Clinical trial of the effect of carnitine supplementation on metabolic profiles in women with polycystic ovary syndrome

Protocol summary

Study aim
The aim of the current study is to evaluate the effects of carnitine supplementation on metabolic profiles in women with polycystic ovary syndrome (PCOS).

Design
Study design: Parallel double-blind (both patients and researchers) randomized controlled clinical trial.

Settings and conduct
Population and sample size: 60 patients with PCOS among women of eligible and referred to Taleghani Clinic affiliated to Arak University of Medical Sciences, Arak, 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: Hyperprolactinaemia, diabetes mellitus (DM), thyroid disease, subjects following a special diet or consuming drugs with an effect onhormonal profile like oral conceptives (OCP), ovulation induction agents and anti-obesity therapies in the last 3 months.

Intervention groups
Intervention: Patients will be assigned to receive either carnitine supplements (intervention group: n=30) or placebo (control group: n=30).

Main outcome variables
Outcomes: Markers of insulin metabolism (primary outcomes) and lipid and hormone profiles (secondary outcome) will be quantified at study baseline and end-of-trial.

General information

Reason for update

Acronym

IRCT registration information
IRCT registration number: **IRCT201508025623N49**
Registration date: **2015-08-25, 1394/06/03**
Registration timing: **retrospective**
Last update: **2019-09-28, 1398/07/06**
Update count: **1**

Registration date
2015-08-25, 1394/06/03

Registrant information

Name
Zatollah Asemi

Name of organization / entity
Kashan University of Medical Sciences

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Iran (Islamic Republic of)

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Recruitment status
Recruitment complete

Funding source
Arak University of Medical Sciences

Expected recruitment start date
2015-06-03, 1394/03/13

Expected recruitment end date
2015-06-30, 1394/04/09

Actual recruitment start date
empty

Actual recruitment end date
empty

Trial completion date
empty

Scientific title
Clinical trial of the effect of carnitine supplementation on metabolic 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:

Women aged 18-40 years Patients with PCOS according to Rotterdam criteria

Exclusion criteria:

Hyperprolactinaemia Diabetes mellitus (DM) Thyroid disease Subjects following a special diet or consuming drugs with an effect onhormonal profile like oral conceptives (OCP), ovulation induction agents and anti-obesity therapies in the last 3 months

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: **60**

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 carnitine supplementation (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

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

Arak University of Medical Sciences

Street address

Vice chancellor for research, Arak University of Medical Sciences, Sardasht Avenue, Arak

City

Arak

Province

Markazi

Postal code

3814113634

Approval date

2015-06-02, 1394/03/12

Ethics committee reference number

IR.ARAKMU.REC.1394.113

Health conditions studied

1

Description of health condition studied

Polycystic ovary syndrome

ICD-10 code

E28.2

ICD-10 code description

Sclerocystic ovary syndrome Stein-Leventhal syndrome

Primary outcomes

1

Description

Insulin

Timepoint

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

Method of measurement

Elisa

2

Description

Insulin resistance

Timepoint

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

Method of measurement

Calculation

Secondary outcomes

1

Description

Triglycerides

Timepoint

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

Method of measurement

Enzymatic

2

Description

HDL-cholesterol

Timepoint

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

Method of measurement

Enzymatic

3

Description
Total cholesterol
Timepoint
At the beginning of the study and after 12 weeks of intervention
Method of measurement
Enzymatic

4

Description
Fasting blood sugar
Timepoint
At the beginning of the study and after 12 weeks of intervention
Method of measurement
Enzymatic

5

Description
Free testosterone
Timepoint
At the beginning of the study and after 12 weeks of intervention
Method of measurement
Elisa kit

6

Description
LDL
Timepoint
At the beginning of the study and after 12 weeks of intervention
Method of measurement
Enzymatic kit

7

Description
VLDL
Timepoint
At the beginning of the study and after 12 weeks of intervention
Method of measurement
Enzymatic kit

8

Description
Dehydroepiandrosterone sulphate (DHEAS)
Timepoint
At the beginning of the study and after 12 weeks of intervention
Method of measurement
Enzymatic kit

Intervention groups

1

Description
Intervention group: Carnitine tablet, 250 mg, daily, for 12 weeks orally.
Category
Treatment - Drugs

2

Description
Control group: Placebo tablet, daily, for 12 weeks orally.
Category
Treatment - Drugs

Recruitment centers

1

Recruitment center
Name of recruitment center
Taleghani Clinic
Full name of responsible person
Mehri Jamilian
Street address
Emam Khomeyni Avenue, Arak
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Isfehan
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3814113634
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Sponsors / Funding sources

1

Sponsor
Name of organization / entity
Arak University of Medical Sciences
Full name of responsible person
Mohammad Rafiee
Street address
Vice chancellor for research, Arak University of Medical Sciences, Sardasht Avenue, Arak
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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
Arak 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
PhD of Nutrition
Latest degree
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Other areas of specialty/work
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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