

Clinical Trial Protocol

Iranian Registry of Clinical Trials

16 Jul 2026

Clinical trial of the effect of carnitine supplementation compared with the placebo on mental health parameters and biomarkers of oxidative stress in women with polycystic ovary syndrome

Protocol summary

Study aim

The aim of this study is to determine the effects of carnitine supplementation on mental health parameters and biomarkers of oxidative stress in patients with polycystic ovary syndrome.

Design

Study design: Parallel double-blind (both patients and researchers) randomized controlled clinical trial. Random assignment will be done by the use of computer-generated random numbers.

Settings and conduct

Population and sample size: 60 patients with polycystic ovary syndrome of eligible and referred to Kosar 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 polycystic ovary syndrome and aged 18 to 40 years will be included in this study. Exclusion criteria: Pregnant women, individuals with metabolic diseases, thyroid disease, hyperprolactinemia, hypercortisolemia and renal and liver diseases

Intervention groups

Intervention: Patients will be assigned to receive either carnitine (n=30) or placebo (n=30). Carnitine and placebo capsules are similar in shape and size.

Main outcome variables

Outcomes: Parameters of mental health (primary outcomes) and biomarkers of oxidative stress (secondary outcome) will be quantified at study baseline and end-of-trial.

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT201605225623N81**

Registration date: **2016-05-29, 1395/03/09**

Registration timing: **retrospective**

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

Update count: **1**

Registration date

2016-05-29, 1395/03/09

Registrant information

Name

Zatollah Asemi

Name of organization / entity

Kashan University of Medical Sciences

Country

Iran (Islamic Republic of)

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Recruitment status

Recruitment complete

Funding source

Vice chancellor for research, Arak University of Medical Sciences

Expected recruitment start date

2016-03-08, 1394/12/18

Expected recruitment end date

2016-03-26, 1395/01/07

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 mental health parameters and biomarkers of oxidative stress 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:**

Patients with PCOS according to Rotterdam criteria Aged 18 to 40 years

Exclusion criteria:

Pregnant women Individuals with metabolic diseases
Thyroid disease Hyperprolactinemia Hypercortisolemia
Renal and liver diseases

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

Random assignment will be done by the use of computer-generated random numbers.

Secondary Ids

empty

Ethics committees**1****Ethics committee****Name of ethics committee**

Ethics committee of Arak University of Medical Sciences

Street address

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

City

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Province

Markazi

Postal code

3814113634

Approval date

2016-03-07, 1394/12/17

Ethics committee reference number

IR.ARAKMU.REC.1394.372

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**

Beck score

Timepoint

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

Method of measurement

Questionnaire

2**Description**

GHQ score

Timepoint

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

Method of measurement

Questionnaire

3**Description**

DASS-28 score

Timepoint

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

Method of measurement

Questionnaire

Secondary outcomes

1

Description

Total antioxidant

Timepoint

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

Method of measurement

Spectrophotometry

2

Description

malondialdehyde

Timepoint

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

Method of measurement

Spectrophotometry

3

Description

Glutathione

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

Kosar Clinic

Full name of responsible person

Mehri Jamilian

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Emam Khomeyni Avenue, Arak

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Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Vice chancellor for research, Arak University of Medical Sciences

Full name of responsible person

Mohammad Rafiee

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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

Vice chancellor for research, 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

Ph.D.

Other areas of specialty/work

Nutrition

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Person responsible for scientific inquiries**Contact****Name of organization / entity**

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Web page address**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