Clinical Trial Protocol
Iranian Registry of Clinical Trials

30 Jul 2026

Clinical trial of the effect of combined chromium and carnitine supplementation on hormonal profiles, inflammatory factors, oxidative stress biomarkers and gene expression related to inflammation in women with polycystic ovary syndrome

Protocol summary

Study aim

Objective: The aim of this study is to determine the effects of combined chromium and carnitine supplementation on hormonal profiles, inflammatory factors and oxidative stress biomarkers and gene expression related to inflammation in patients with polycystic ovary syndrome (PCOS).

Design

Clinical trial with control group, with parallel groups, double-blind, randomised, 60 patients, phase 3.

Settings and conduct

Among patients with polycystic ovary syndrome referred to Kosar outpatient Clinic affiliated to Arak University of Medical Sciences, 60 patients will be selected according to inclusion and exclusion criteria. Participants, investigators or the assessors of the outcomes are unaware of the study groups. Supplements and placebos are similar in shape and size. Fasting blood samples will be taken at baseline and 12 weeks after the intervention. At the beginning and the end of the intervention: 12 weeks

Participants/Inclusion and exclusion criteria

Inclusion criteria: Patients with polycystic ovary syndrome aged 18 to 40 years. Exclusion criteria: Pregnancy, adrenal hyperplasia, androgen-secreting tumors, hyperprolactinemia, thyroid dysfunction, diabetes.

Intervention groups

Intervention group: 1000 mg carnitine (Avecina,Tehran, Iran) and 200 µg chromium (21st Century, Arizona, USA) daily for 12 weeks orally. Control group: Placebo capsule (Barij Essence, Kashan, Iran), daily for 12 weeks orally.

Main outcome variables

Total testosterone (primary outcome) and inflammatory factors, oxidative stress biomarkers and gene expression related to inflammation (secondary outcomes) .

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT2017090533941N24**
Registration date: **2017-11-13, 1396/08/22**
Registration timing: **retrospective**

Last update: **2019-09-21, 1398/06/30**
Update count: **1**

Registration date

2017-11-13, 1396/08/22

Registrant information

Name

Mohammadreza Sharif

Name of organization / entity

Country

Iran (Islamic Republic of)

Phone

+98 31 5546 3378

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ostadmohammadi-vr@kaums.ac.ir

Recruitment status

Recruitment complete

Funding source

Vice chancellor for research, Arak University of Medical Sciences

Expected recruitment start date

2017-10-30, 1396/08/08

Expected recruitment end date

2017-11-13, 1396/08/22

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Clinical trial of the effect of combined chromium and carnitine supplementation on hormonal profiles, inflammatory factors, oxidative stress biomarkers and gene expression related to inflammation in women with polycystic ovary syndrome

Public title

Effect of combined chromium and carnitine supplementation in treatment of women with polycystic ovary syndrome

Purpose

Treatment

Inclusion/Exclusion criteria

Inclusion criteria:

Patients with polycystic ovary syndrome aged 18 to 40 years

Exclusion criteria:

Pregnancy Adrenal hyperplasia Androgen-secreting tumors Hyperprolactinemia Thyroid dysfunction Diabetes

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

Participants in each block will be randomly allocated into two treatment groups to take either combined chromium and carnitine supplementation (n = 30) or placebo (n = 30). Randomization will be done by the use of Stat Trek software. Participants, investigators or the assessors of the outcomes are also unaware of the study groups. https://stattrek.com/statistics/random-number-generator.aspx

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 Kosar outpatient 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 Arak University of Medical Sciences

Street address

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

City

Arak

Province

Markazi

Postal code

3817793163

Approval date

2017-10-29, 1396/08/07

Ethics committee reference number

IR.ARAKMU.REC.1396.146

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

Total testosterone

Timepoint

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

Method of measurement

Elisa kit

Secondary outcomes

1

Description

Nitric oxide

Timepoint

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

Method of measurement

Spectrophotometry

2

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

3

Description
Hs-CRP
Timepoint
At the beginning of the study and after 12 weeks of intervention
Method of measurement
Elisa kit

4

Description
Malondialdehyde
Timepoint
At the beginning of the study and after 12 weeks of intervention
Method of measurement
Spectrophotometry

5

Description
Glutathione
Timepoint
At the beginning of the study and after 12 weeks of intervention
Method of measurement
Spectrophotometry

6

Description
Total antioxidant capacity
Timepoint
At the beginning of the study and after 12 weeks of intervention
Method of measurement
Spectrophotometry

7

Description
Expressed levels of IL-6 gene
Timepoint
At the beginning of the study and after 12 weeks of intervention
Method of measurement
PCR

8

Description
Expressed levels of TGFB gene
Timepoint
At the beginning of the study and after 12 weeks of intervention
Method of measurement
PCR

9

Description
Expressed levels of TNF-a gene
Timepoint
At the beginning of the study and after 12 weeks of intervention
Method of measurement
PCR

10

Description
Beck depression inventory
Timepoint
At the beginning of the study and after 12 weeks of intervention
Method of measurement
Questionnaire

11

Description
General health questionnaire
Timepoint
At the beginning of the study and after 12 weeks of intervention
Method of measurement
Questionnaire

12

Description
Depression anxiety and stress scale
Timepoint
At the beginning of the study and after 12 weeks of intervention
Method of measurement
Questionnaire

13

Description
Modified Ferriman Gallwey
Timepoint
At the beginning of the study and after 12 weeks of intervention
Method of measurement
Questionnaire

Intervention groups

1

Description
Intervention group: 200 µg chromium (21st Century, Arizona, USA) and 1000 mg carnitine (Avecina, Tehran,

Iran) daily for 12 weeks orally.

Category

Treatment - Drugs

2

Description

Control group: Placebo (Barij Essence, Kashan, Iran), daily 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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jamilian.mehri@gmail.com

Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Vice chancellor for research, Arak University of Medical Sciences

Full name of responsible person

Mohammad Arjomandzadegan

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arjomandzadegan-a@aums.ac.ir

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

Ph.D of Nutrition

Latest degree

Ph.D.

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

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