

Clinical Trial Protocol

Iranian Registry of Clinical Trials

01 Aug 2026

Clinical trial of the effect of combined chromium and carnitine supplementation on metabolic profiles and gene expression related to insulin and lipid 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 metabolic profiles and gene expression related to insulin and lipid in women with polycystic ovary syndrome.

Design

Study design: Randomized double-blind placebo-controlled trial. Randomization will be done by the use of computer-generated random numbers. Patients will be assigned into two groups to receive supplements (n=30) or placebo (n=30).

Settings and conduct

Among patients with polycystic ovary syndrome referred to Taleghani 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: 200 µg chromium (21st Century, Arizona, USA) and 1000 mg carnitine (Avecina, Tehran, Iran) daily for 12 weeks orally. Control group: Placebo (Barij Essence, Kashan, Iran), daily for 12 weeks orally.

Main outcome variables

Outcomes: Markers of insulin metabolism (primary outcomes) and lipid profiles and gene expression related

to insulin and lipid (secondary outcomes) will be quantified at study baseline and end-of-trial.

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20170513033941N38**

Registration date: **2018-09-26, 1397/07/04**

Registration timing: **retrospective**

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

Update count: **1**

Registration date

2018-09-26, 1397/07/04

Registrant information

Name

Mohammadreza Sharif

Name of organization / entity

Country

Iran (Islamic Republic of)

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ostadmohammadi-vr@kaums.ac.ir

Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2018-06-11, 1397/03/21

Expected recruitment end date

2018-06-26, 1397/04/05

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 metabolic profiles and gene expression related to insulin and lipid 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:
Inclusion criteria: Patients with polycystic ovary syndrome Individuals aged 18 to 40 years.
Exclusion criteria:
Pregnancy Adrenal hyperplasia Androgen-secreting tumors Thyroid dysfunction Diabetes Hyperprolactinemia

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
To decrease potential confounding effects, after balanced randomisation, participants will be allocated into two treatment groups to take either supplements or placebo. Randomization will be done by the use of computer software.

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
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
1771844351
Approval date
2018-06-10, 1397/03/20
Ethics committee reference number
IR.ARAKMU.REC.1397.079

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
Insulin resistance
Timepoint
At the beginning of the study and after 12 weeks of intervention
Method of measurement
Calculation using HOMA formula

2

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

Secondary outcomes

1

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

Method of measurement

Enzymatic kit

2

Description

HDL

Timepoint

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

Method of measurement

Enzymatic kit

3

Description

Triglycerides

Timepoint

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

Method of measurement

Enzymatic kit

4

Description

Expressed levels of PPAR-γ gene

Timepoint

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

Method of measurement

PCR

5

Description

Expressed levels of GLUT-1 gene

Timepoint

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

Method of measurement

PCR

6

Description

Expressed levels of LDL-R gene

Timepoint

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

Method of measurement

PCR

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

Placebo

Recruitment centers

1

Recruitment center

Name of recruitment center

Taleghani outpatient Clinic

Full name of responsible person

Mehri Jamilian

Street address

Emam Khomeyni Avenue, Arak

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1771844351

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jamilian.mehri@gmail.com

Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Arak University of Medical Sciences

Full name of responsible person

Mohammad Arjomandzadegan

Street address

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

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Arjomandzadegan.M@gmail.com

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
Ph.D of Nutrition
Latest degree
Ph.D.
Other areas of specialty/work
Nutrition
Street address
Ghotbe Ravandi Boulevard, Kashan
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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