Clinical Trial Protocol
Iranian Registry of Clinical Trials

18 Sep 2026

Effects of chromium supplementation on metabolic profiles in women with polycystic ovary syndrome

Protocol summary

Study aim

Objective: The aim of this study is to determine the effects of chromium supplementation on metabolic profiles in women with polycystic ovary syndrome (PCOS).

Design

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

Settings and conduct

Population and sample size: Among patients with PCOS referred to Taleghani and Emam Reza Clinics affiliated to Arak University of Medical Sciences, 64 patients will be selected according to inclusion and eclusion criteria.

Participants/Inclusion and exclusion criteria

Inclusion criteria: Patients with PCOS according to Rotterdam criteria and aged 18 to 40 years. Exclusion criteria: Women with hyperprolactinemia, diabetes mellitus, thyroid disease, adrenal hyperplasia, consumed effective drugs on hormonal profile, ovulation induction agents, consuming anti-obesity and antidepressant drugs in the last 3 months (before enrollment).

Intervention groups

Intervention: Patients will be assigned into two groups to receive 200 mcg chromium supplements (n=32) or placebo (n=32) daily. Chromium supplements and placebos capsules are similar in shape and size.

Main outcome variables

Markers of insulin metabolism (primary outcomes) and lipid profiles (secondary outcome)

General information

Reason for update

Due to an error, the request for an update in our website was conducted after paper published. However, the revisions were accordance with either the original approved proposal or with coordination with Vice Chancellor of Research at the University.

Acronym

IRCT registration information

IRCT registration number: **IRCT201502055623N34**
Registration date: **2015-02-09, 1393/11/20**
Registration timing: **registered_while_recruiting**

Last update: **2019-11-04, 1398/08/13**
Update count: **1**

Registration date

2015-02-09, 1393/11/20

Registrant information

Name
Zatollah Asemi

Name of organization / entity
Kashan University of Medical Sciences

Country
Iran (Islamic Republic of)

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+98 36 1534 3570

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asemi_z@kaums.ac.ir

Recruitment status

Recruitment complete

Funding source

Arak University of Medical Sciences

Expected recruitment start date

2015-02-02, 1393/11/13

Expected recruitment end date

2015-03-01, 1393/12/10

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Effects of chromium supplementation on metabolic

profiles in women with polycystic ovary syndrome

Public title
Effect of supplementation in treatment of polycystic ovary syndrome
Purpose
Treatment
Inclusion/Exclusion criteria
Inclusion criteria:
Women aged 18-40 years diagnosed with PCOS
Exclusion criteria:
Women with hyperprolactinemia Diabetes mellitus Thyroid disease Adrenal hyperplasia Consumed effective drugs on hormonal profile Ovulation induction agents Anti-obesity and antidepressants in the last 3 months before enrollment
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: **64**
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 supplementation (n=32) or placebo (n=32). 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. Chromium supplements and placebos capsules are similar in shape and size.
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 Education and Research, Sardasht Avenue, Arak
City
Arak
Province
Markazi
Postal code
3848176341
Approval date
2015-02-01, 1393/11/12
Ethics committee reference number
93-174-21

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 8 weeks of the intervention
Method of measurement
Calculation with HOMA formula

Secondary outcomes

1

Description
Insulin
Timepoint
At the beginning of the study and after 8 weeks of intervention
Method of measurement
ELISA kit

2

Description
Cholesterol
Timepoint
At the beginning of the study and after 8 weeks of intervention
Method of measurement
Enzymatic kit

3

Description
HDL-cholesterol

Timepoint
At the beginning of the study and after 8 weeks of intervention
Method of measurement
Enzymatic kit

4

Description
Triglycerides
Timepoint
At the beginning of the study and after 8 weeks of intervention
Method of measurement
Enzymatic kit

5

Description
VLDL
Timepoint
At the beginning of the study and after 8 weeks of intervention
Method of measurement
Enzymatic kit

6

Description
LDL
Timepoint
At the beginning of the study and after 8 weeks of intervention
Method of measurement
Enzymatic kit

7

Description
FPG
Timepoint
At the beginning of the study and after 8 weeks of intervention
Method of measurement
Enzymatic kit

Intervention groups

1

Description
Intervention group: Chromium tablet, 200 µg, daily, for 8 weeks orally.
Category
Treatment - Drugs

2

Description
Control group: Placebo tablet, daily, for 8 weeks orally.
Category
Treatment - Drugs

Recruitment centers

1

Recruitment center
Name of recruitment center
Taleghani and Emam Reza Clinics
Full name of responsible person
Mehri Jamilian
Street address
Emam Khomeyni Avenue, Arak
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Postal code
3814113634
Phone
+98 86 3223 3823
Email
jamilian.m@gmail.com

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 Education and Research, Sardasht Avenue, Arak
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rafiee-m@aums.ac.ir
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
Associate professor

Latest degree
Ph.D.

Other areas of specialty/work
Nutrition

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Person responsible for scientific inquiries

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Position
Nutrition PhD

Latest degree
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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