

# Clinical Trial Protocol

## Iranian Registry of Clinical Trials

29 May 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 exclusion 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)

##### Phone

+98 36 1534 3570

##### Email address

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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Arak

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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

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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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## 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