Clinical Trial Protocol
Iranian Registry of Clinical Trials

17 Sep 2026

Clinical trial of the effect of chromium supplementation compared with the placebo on metabolic profiles in women with polycystic ovary syndrome of IVF candidate

Protocol summary

Study aim

The aim of this study is to determine the effects of chromium supplementation on metabolic profiles in patients of polycystic ovary syndrome of IVF candidate.

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 chromium supplements (n=20) or placebo (n=20).

Settings and conduct

Among patients with polycystic ovary syndrome candidate for IVF referred to Kosar outpatient Clinic affiliated to Arak University of Medical Sciences, 40 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 8 weeks after the intervention. At the beginning and the end of the intervention: 8 weeks.

Participants/Inclusion and exclusion criteria

Inclusion criteria: patients with polycystic ovary syndrome candidate for IVF aged 18 to 40 years. Exclusion criterion: Androgen-secreting tumors, thyroid dysfunction, diabetes or impaired glucose tolerance.

Intervention groups

Intervention group: Chromium supplements (Nature Made, California, USA), 200 µg, daily, for 8 weeks orally. Control group: Placebo (Barij Essence, Kashan, Iran) once a day for 8 weeks orally.

Main outcome variables

Outcomes: Glycemic control (primary outcomes) and lipid profiles and biomarkers of inflammation and 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: **IRCT201706075623N120**
Registration date: **2017-06-22, 1396/04/01**
Registration timing: **retrospective**

Last update: **2019-09-11, 1398/06/20**
Update count: **1**

Registration date

2017-06-22, 1396/04/01

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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Recruitment status

Recruitment complete

Funding source

Vice chancellor for research, Arak University of Medical Sciences

Expected recruitment start date

2017-05-23, 1396/03/02

Expected recruitment end date

2017-06-10, 1396/03/20

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Clinical trial of the effect of chromium supplementation compared with the placebo on metabolic profiles in women with polycystic ovary syndrome of IVF candidate

Public title

Effect of supplementation in treatment of women with polycystic ovary syndrome of IVF candidate

Purpose

Treatment

Inclusion/Exclusion criteria

Inclusion criteria:

Patients with polycystic ovary syndrome Individuals aged 18 to 40 years old

Exclusion criteria:

Androgen-secreting tumors Thyroid dysfunction Diabetes or impaired glucose tolerance

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: **40**

Randomization (investigator's opinion)

Randomized

Randomization description

At study baseline, after ratification based on age and BMI, subjects will be randomly allocated into two groups to receive supplements or placebo. 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

Randomization 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

Arak

Province

Markazi

Postal code

3848176941

Approval date

2017-05-22, 1396/03/01

Ethics committee reference number

IR.ARAKMU.REC.1396.50

Health conditions studied

1

Description of health condition studied

Polycystic ovarian syndrome

ICD-10 code

E28.2

ICD-10 code description

Polycystic ovarian syndrome

Primary outcomes

1

Description

Insulin

Timepoint

At the beginning of the study and after 8 weeks of intervention

Method of measurement

Elisa kit

2

Description

Insulin resistance

Timepoint

At the beginning of the study and after 8 weeks of intervention

Method of measurement

Using HOMA formula

Secondary outcomes

1

Description

Total cholesterol

Timepoint

At the beginning of the study and after 8 weeks of intervention

Method of measurement
Enzymatic kit

2

Description
Triglycerides
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
Total antioxidant capacity
Timepoint
At the beginning of the study and after 8 weeks of intervention
Method of measurement
Spectrophotometry

5

Description
Total glutathione
Timepoint
At the beginning of the study and after 8 weeks of intervention
Method of measurement
Spectrophotometry

6

Description
Malondialdehyde
Timepoint
At the beginning of the study and after 8 weeks of intervention
Method of measurement
Spectrophotometry

Intervention groups

1

Description
Intervention group: Chromium supplements (Nature Made, California, USA), 200 µg, daily, for 8 weeks orally.
Category
Treatment - Drugs

2

Description
Control group: Placebo (Barij Essence, Kashan, Iran) once a day for 8 weeks orally.
Category
Treatment - Drugs

Recruitment centers

1

Recruitment center
Name of recruitment center
Kosar Clinic
Full name of responsible person
Mehri Jamilian
Street address
Emam Khomeyni Avenue, Arak
City
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Postal code
3848176941
Phone
+98 86 3417 3502
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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 Rafiee
Street address
Vice chancellor for research, Arak University of Medical Sciences, Sardasht Avenue, Arak
City
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Province
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Postal code
3848176941
Phone
+98 86 3417 3502
Email
Mohammad.Rafiee22@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

Private

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

Street address

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Person responsible for scientific inquiries

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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

Not applicable

Informed Consent Form

Undecided - It is not yet known if there will be a plan to make this available

Clinical Study Report

Not applicable

Analytic Code

Not applicable

Data Dictionary

Not applicable