

Clinical Trial Protocol

Iranian Registry of Clinical Trials

20 Jul 2026

Clinical trial of the effect of chromium supplementation compared with the placebo on gene expression related to insulin and lipid in women with polycystic ovary syndrome candidate for IVF

Protocol summary

Study aim

The aim of this study is to determine the effects of chromium supplementation on gene expression related to insulin and lipid in patients with polycystic ovary syndrome candidate for IVF.

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 Taleghani Clinic affiliated to Shahid Beheshti 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: 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

Gene expression related to insulin (primary outcomes) and gene expression related to 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: **IRCT20170513033941N32**

Registration date: **2018-04-05, 1397/01/16**

Registration timing: **retrospective**

Last update: **2019-09-13, 1398/06/22**

Update count: **1**

Registration date

2018-04-05, 1397/01/16

Registrant information

Name

Mohammadreza Sharif

Name of organization / entity

Country

Iran (Islamic Republic of)

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+98 31 5546 3378

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ostadmohammadi-vr@kaums.ac.ir

Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2018-02-27, 1396/12/08

Expected recruitment end date

2018-03-11, 1396/12/20

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 gene expression related to insulin and lipid in women with polycystic ovary syndrome candidate for IVF

Public title

Effect of chromium supplementation in treatment of patients with polycystic ovary syndrome candidate for IVF

Purpose

Treatment

Inclusion/Exclusion criteria

Inclusion criteria:

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

Exclusion criteria:

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 balanced randomisation, subjects will be 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

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee

Ethics committee of Shahid Beheshti University of Medical Sciences

Street address

Shahid Beheshti University of Medical Sciences,
Yaman st, Velenjak, Chamran highway

City

Tehran

Province

Tehran

Postal code

1771844351

Approval date

2018-02-26, 1396/12/07

Ethics committee reference number

IR.SBMU.RETECH.REC.1396.1292

Health conditions studied

1

Description of health condition studied

Polycystic ovary syndrome

ICD-10 code

Polycystic

ICD-10 code description

E28.2

Primary outcomes

1

Description

Expressed levels of PPAR-γ gene

Timepoint

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

Method of measurement

PCR

2

Description

Expressed levels of GLUT-1 gene

Timepoint

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

Method of measurement

PCR

Secondary outcomes

1

Description

Expressed levels of LDLR gene

Timepoint

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

Method of measurement

PCR

2

Description

Expressed levels of TNF- α gene
Timepoint
At the beginning of the study and after 8 weeks of intervention
Method of measurement
PCR

3

Description
Expressed levels of IL-1 gene
Timepoint
At the beginning of the study and after 8 weeks of intervention
Method of measurement
PCR

4

Description
Expressed levels of IL-8 gene
Timepoint
At the beginning of the study and after 8 weeks of intervention
Method of measurement
PCR

5

Description
Expressed levels of TGF- β gene
Timepoint
At the beginning of the study and after 8 weeks of intervention
Method of measurement
PCR

6

Description
Expressed levels of VEGF gene
Timepoint
At the beginning of the study and after 8 weeks of intervention
Method of measurement
PCR

Intervention groups

1

Description
Intervention group: Chromium supplements (Nature Made, California, USA), 200 μ g, 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

Placebo

Recruitment centers

1

Recruitment center
Name of recruitment center
Taleghani Clinic
Full name of responsible person
Dr. Sharzadzade Modarres
Street address
Taleghani hospital, Yaman st, Velenjak, Chamran highway
City
Tehran
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Tehran
Postal code
1771844351
Phone
+98 21 2243 2560
Email
Modarres.sh@gmail.com

Sponsors / Funding sources

1

Sponsor
Name of organization / entity
Shahid Beheshti University of Medical Sciences
Full name of responsible person
Afshin Zarghi
Street address
Shahid Beheshti University of Medical Sciences, Yaman st, Velenjak, Chamran highway
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1771844351
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Zarghi.A@gmail.com
Grant name
Grant code / Reference number
Is the source of funding the same sponsor organization/entity?
Yes
Title of funding source
Shahid Beheshti 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.
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Person responsible for updating data

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Web page address

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