Clinical Trial Protocol
Iranian Registry of Clinical Trials

20 Nov 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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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 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

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

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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

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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.
Other areas of specialty/work
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Person responsible for updating data

Contact
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8115187159
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asemi_z@kaums.ac.ir
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