

Clinical Trial Protocol

Iranian Registry of Clinical Trials

27 Jul 2026

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

Protocol summary

Study aim

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

Design

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

Settings and conduct

Population and sample size: Among patients with polycystic ovary syndrome referred to Mahdiah Clinic affiliated to Shahid Beheshti University of Medical Sciences, 40 patients will be selected according to inclusion and exclusion criteria.

Participants/Inclusion and exclusion criteria

Inclusion criteria: Patients with PCOS of IVF candidate according to Rotterdam criteria and aged 18 to 40 years will be included in this study. Exclusion criteria: Pregnant women Participants with elevated levels of prolactin Thyroid disorder Endocrine diseases.

Intervention groups

Intervention: Patients will be assigned into two groups to receive selenium (n=20) or placebo (n=20). Selenium and placebos capsules are similar in shape and size. At the beginning and end of the intervention: 8 weeks.

Main outcome variables

Gene expression of PPAR- γ and glucose transporter 1 (GLUT-1) (primary outcomes) and gene expression levels of low-density lipoprotein receptor (LDLR) and lipoprotein(a) [LP(a)] (secondary outcomes) will be quantified at study baseline and end-of-trial.

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT201704245623N113**

Registration date: **2017-05-06, 1396/02/16**

Registration timing: **retrospective**

Last update: **2019-09-19, 1398/06/28**

Update count: **1**

Registration date

2017-05-06, 1396/02/16

Registrant information

Name

Zatollah Asemi

Name of organization / entity

Kashan University of Medical Sciences

Country

Iran (Islamic Republic of)

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Email address

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Recruitment status

Recruitment complete

Funding source

Vice chancellor for research, Shahid Beheshti University of Medical Sciences

Expected recruitment start date

2016-04-16, 1395/01/28

Expected recruitment end date

2016-05-09, 1395/02/20

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date
empty

Scientific title
Clinical trial of the effect of selenium supplementation compared with the placebo on gene expression related to insulin and lipid 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 PCOS of IVF candidate according to Rotterdam criteria Aged 18 to 40 years
Exclusion criteria:
 Pregnant women Participants with elevated levels of prolactin Thyroid disorder Endocrine diseases

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 and after stratification for pre-intervention BMI and age, subjects will be randomly divided into two groups to take either selenium supplements (n=20) or placebo (n=20). 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
 Vice chancellor for research, Shahid Beheshti University of Medical Sciences
Street address
 Shahid Beheshti University of Medical Sciences, Velenjak
City
 Tehran
Province
 Tehran
Postal code
 021 2243 9770
Approval date
 2016-04-15, 1395/01/27
Ethics committee reference number
 IR.SBMU.REC.1396.33

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
 Expressed levels of PPAR-γ

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

Method of measurement
 PCR

2

Description
 Expressed levels of GLUT-1

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

Method of measurement
 PCR

Secondary outcomes

1

Description
 Expressed levels of Lp(a) gene

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

Method of measurement

PCR

2

Description

Expressed levels of LDLR gene

Timepoint

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

Method of measurement

PCR

Intervention groups

1

Description

Intervention group: Selenium supplements (Nature, California, USA), 200 µg, daily, for 8 weeks orally.

Category

Treatment - Drugs

2

Description

Control group: Placebo capsule, daily for 8 weeks orally.

Category

Treatment - Drugs

Recruitment centers

1

Recruitment center

Name of recruitment center

Infertility Center of Mahdiah Hospital

Full name of responsible person

Zahra Heidar

Street address

Fadaeean Eslam street, Shoosh square

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Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Vice chancellor for research, 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

Vice chancellor for research, 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

PhD of Nutrition

Latest degree

Ph.D.

Other areas of specialty/work

Nutrition

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Person responsible for scientific inquiries

Contact

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Position

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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

Person responsible for updating data

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.