

Clinical Trial Protocol

Iranian Registry of Clinical Trials

29 Jul 2026

Clinical trial of the effect of selenium supplementation compared with the placebo on gene expression related to inflammation in women with polycystic ovary syndrome candidate for IVF.

Protocol summary

Study aim

Objective: The aim of this study is to determine the effects of selenium supplementation on gene expression related to inflammation in patients with polycystic ovary syndrome candidate for IVF

Design

Study 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

Among patients with polycystic ovary syndrome candidate for IVF referred to Mahdiah Clinic affiliated to Shahid Beheshti University of Medical Sciences, Tehran, Iran, 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 criteria: Metabolic abnormalities such as diabetes, impaired glucose tolerance and thyroid dysfunction.

Intervention groups

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

Main outcome variables

Outcomes: Expressed levels of TNF-α gene (primary outcome) and gene expression related to other inflammatory factors (secondary outcomes) will be

quantified at study baseline and end-of-trial.

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20170513033941N23**

Registration date: **2017-12-20, 1396/09/29**

Registration timing: **registered_while_recruiting**

Last update: **2019-09-15, 1398/06/24**

Update count: **1**

Registration date

2017-12-20, 1396/09/29

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

2017-12-11, 1396/09/20

Expected recruitment end date

2017-12-30, 1396/10/09

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 inflammation in women with polycystic ovary syndrome candidate for IVF.

Public title

Effect of selenium supplementation in the treatment of women with polycystic ovary syndrome candidate for IVF.

Purpose

Treatment

Inclusion/Exclusion criteria**Inclusion criteria:**

Inclusion criteria: Patients with polycystic ovary syndrome. Individuals aged 18 to 40 years.

Exclusion criteria:

Exclusion criteria: Metabolic abnormalities such as diabetes, impaired glucose tolerance and thyroid dysfunction

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 (<25 and ≥ 25 kg/m²) and age (<30 and ≥ 30 y), subjects will be randomly divided into two groups to receive supplement 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, Velenjak

City

Tehran

Province

Tehran

Postal code

1985717443

Approval date

2017-12-10, 1396/09/19

Ethics committee reference number

IR.SBMU.RETECH.REC.1396.737

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 TNF-a 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 IL-1 gene

Timepoint

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

Method of measurement

PCR

2**Description**

Expressed levels of IL-8 gene

Timepoint

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

Method of measurement

PCR

3**Description**

Expressed levels of VEGF

Timepoint

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

Method of measurement

PCR

4**Description**

Expressed levels of TGF-B

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 (Barij Essence, Kashan, Iran), daily, for 8 weeks orally.

Category

Placebo

Recruitment centers**1****Recruitment center****Name of recruitment center**

Infertility Center of Mahdiah Hospital

Full name of responsible person

Zahra Heidari

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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

Nutritionist

Latest degree

Ph.D.

Other areas of specialty/work

Nutrition

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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