Clinical Trial Protocol
Iranian Registry of Clinical Trials

20 Nov 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 Mahdieh 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-a 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)

Phone

+98 31 5546 3378

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ostadmohammadi-vr@kaums.ac.ir

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 Mahdieh Hospital
Full name of responsible person
Zahra Heidar
Street address
Fadaeean Eslam St, Shoosh SQ
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1985717443
Phone
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Email
Heidar.Zahra@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, Velenjak
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Email
Zarghi.afshin@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
Nutritionist
Latest degree
Ph.D.
Other areas of specialty/work
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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