

Clinical Trial Protocol

Iranian Registry of Clinical Trials

13 Jun 2026

Effects of selenium supplementation on insulin metabolism and lipid profiles in women with polycystic ovary syndrome

Protocol summary

Study aim

The aim of this study is to determine the effects of selenium supplementation on insulin and inflammatory factor in women with polycystic ovary syndrome (PCOS).

Design

Study design: parallel double-blind randomized controlled clinical trial.

Settings and conduct

Population and sample size: 70 women with PCOS eligible and referred to Kossar Clinic affiliated to Arak University of Medical Sciences, Arak, Iran in the study will be selected.

Participants/Inclusion and exclusion criteria

Inclusion criteria: Patients with PCOS according to Rotterdam criteria and aged 18 to 40 years will be included in this study. Exclusion criteria: Menopause, consumed selenium supplements and metformin in the last 3 months, diabetic, hypothyroidism, used tobacco, taking a special diet or effective drugs on hormonal profile like oral contraceptive (OCP) and ovulation induction agents.

Intervention groups

Intervention: Patients will be assigned to receive either 200 µg selenium supplement (intervention group: n=35) or placebo (control group: n=35).

Main outcome variables

Insulin resistance (primary outcome) and lipid profiles (secondary outcome) will be quantified at study baseline and end-of-trial.

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT201408155623N25**

Registration date: **2014-08-24, 1393/06/02**

Registration timing: **registered_while_recruiting**

Last update: **2019-09-28, 1398/07/06**

Update count: **1**

Registration date

2014-08-24, 1393/06/02

Registrant information

Name

Zatollah Asemi

Name of organization / entity

Kashan University of Medical Sciences

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Recruitment status

Recruitment complete

Funding source

Arak University of Medical Sciences

Expected recruitment start date

2014-08-12, 1393/05/21

Expected recruitment end date

2014-08-26, 1393/06/04

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Effects of selenium supplementation on insulin metabolism and lipid profiles in women with polycystic ovary syndrome

Public title

Effect of supplementation in treatment of polycystic ovary syndrome

Purpose

Treatment

Inclusion/Exclusion criteria

Inclusion criteria:
Women aged 18-40 years Diagnosed with PCOS

Exclusion criteria:
Menopause Consumed selenium supplements and metformin in the last 3 months Diabetic Hypothyroidism Used tobacco Taking a special diet or effective drugs on hormonal profile like oral contraceptive (OCP) and ovulation induction agents.

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: **70**

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=35) or placebo (n=35). 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
Arak University of Medical Sciences

Street address
Vice-chancellor for Education and Research, Sardasht Avenue, Arak

City
Arak

Province
Markazi

Postal code
3819693345

Approval date
2014-08-11, 1393/05/20

Ethics committee reference number
93-166-18

Health conditions studied

1

Description of health condition studied
Polycystic ovary syndrome

ICD-10 code
E28.2

ICD-10 code description
Sclerocystic ovary syndrome Stein-Leventhal syndrome

Primary outcomes

1

Description
Insulin resistance

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

Method of measurement
Eliza

Secondary outcomes

1

Description
Insulin

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

Method of measurement
Elisa kit

2

Description
Insulin sensitivity

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

Method of measurement
Using QUICKI formula

3

Description
Triglycerides

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

Method of measurement
Enzymatic kit

4

Description

Total cholesterol

Timepoint

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

Method of measurement

Enzymatic kit

5

Description

VLDL

Timepoint

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

Method of measurement

Enzymatic kit

6

Description

LDL-cholesterol

Timepoint

At the beginning of the study and after 12 weeks of intervention

Method of measurement

Elisa kit

7

Description

HDL-cholesterol

Timepoint

At the beginning of the study and after 12 weeks of intervention

Method of measurement

Enzymatic kit

Intervention groups

1

Description

Intervention group: Selenium tablet, 200 µg, daily, for 8 weeks orally.

Category

Treatment - Drugs

2

Description

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

Category

Treatment - Drugs

Recruitment centers

1

Recruitment center

Name of recruitment center

Kossar Clinic

Full name of responsible person

Mehri Jamilian

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Sponsors / Funding sources

1

Sponsor**Name of organization / entity**

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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

Arak 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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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