

# Clinical Trial Protocol

## Iranian Registry of Clinical Trials

19 Jun 2026

### Effects of selenium supplementation on hormonal status and biomarkers of oxidative stress in women with polycystic ovary syndrome

#### Protocol summary

##### Study aim

The aim of this study is to determine the effects of selenium supplementation on hormonal status and biomarkers of oxidative stress in women with polycystic ovary syndrome (PCOS).

##### Design

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

##### Settings and conduct

Population and sample size: 64 women with PCOS eligible and referred to Alavi Clinic affiliated to Ardabil University of Medical Sciences, Ardabil, 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: Elevated levels of prolactin, thyroid disorder T2DM, congenital adrenal hyperplasia, had normal baseline renal function tests, bilirubin, and aminotransferases, during the last 3 months before the intervention used any form of oral contraceptives (OCs), steroid hormones, or any other treatments likely to affect ovarian function, insulin sensitivity, or inflammatory factors, biomarkers of oxidative stress.

##### Intervention groups

Intervention: Patients will be assigned to receive either 200 µg selenium supplement (intervention group: n=32) or placebo (control group: n=32).

##### Main outcome variables

Outcomes: Malondialdehyde (primary outcomes) and Hormonal parameters and other metabolic profiles (secondary outcomes)

#### General information

##### Reason for update

##### Acronym

##### IRCT registration information

IRCT registration number: **IRCT201412295623N33**

Registration date: **2015-01-09, 1393/10/19**

Registration timing: **retrospective**

Last update: **2019-09-25, 1398/07/03**

Update count: **1**

##### Registration date

2015-01-09, 1393/10/19

##### Registrant information

###### Name

Zatollah Asemi

###### Name of organization / entity

Kashan University of Medical Sciences

###### Country

Iran (Islamic Republic of)

###### Phone

+98 36 1534 3570

###### Email address

asemi\_z@kaums.ac.ir

##### Recruitment status

**Recruitment complete**

##### Funding source

Ardabil University of Medical Sciences

##### Expected recruitment start date

2014-10-19, 1393/07/27

##### Expected recruitment end date

2014-11-02, 1393/08/11

##### Actual recruitment start date

empty

##### Actual recruitment end date

empty

##### Trial completion date

empty

##### Scientific title

Effects of selenium supplementation on hormonal status and biomarkers of oxidative stress 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:

Elevated levels of prolactin Thyroid disorder T2DM  
Congenital adrenal hyperplasia Had normal baseline renal function tests, bilirubin, and aminotransferases  
During the last 3 months before the intervention used anyform of oral contraceptives (OCPs), steroid hormones, or any other treatments likely to affect ovarian function, insulin sensitivity, or inflammatory factors, biomarkers of oxidative stress.

## 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: **64**

## 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 selenium supplements (n=32) or placebo (n=32). 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

Ardabil University of Medical Sciences

##### Street address

Research Assistance, Ardabil University of Medical Sciences, Ardabil, Iran

#### City

Ardabil

#### Province

Ardabil

#### Postal code

5618985991

#### Approval date

2014-10-18, 1393/07/26

#### Ethics committee reference number

ARUMS.REC.1393.53

## Health conditions studied

### 1

#### Description of health condition studied

Polycystic ovary syndrome

#### ICD-10 code

E28.2

#### ICD-10 code description

Polycystic ovarian syndrome

## Primary outcomes

### 1

#### Description

Malondialdehyde

#### Timepoint

Baseline and End-of-trial

#### Method of measurement

Spectrophotometry

## Secondary outcomes

### 1

#### Description

Prolactin

#### Timepoint

Baseline and End-of-trial

#### Method of measurement

Elisa

### 2

#### Description

FSH

#### Timepoint

Baseline and End-of-trial

#### Method of measurement

Elisa

### 3

#### Description

LH

#### Timepoint

Baseline and End-of-trial

#### Method of measurement

Elisa

#### 4

**Description**

Free testosterone

**Timepoint**

Baseline and End-of-trial

**Method of measurement**

Elisa kit

#### 5

**Description**

Hs-CRP

**Timepoint**

Baseline and End-of-trial

**Method of measurement**

Elisa kit

#### 6

**Description**

Total antioxidant

**Timepoint**

Baseline and End-of-trial

**Method of measurement**

Spectrophotometry

#### 7

**Description**

Glutathione

**Timepoint**

Baseline and End-of-trial

**Method of measurement**

Spectrophotometry

#### 8

**Description**

Nitric oxide

**Timepoint**

Baseline and End-of-trial

**Method of measurement**

Spectrophotometry

## Intervention groups

#### 1

**Description**

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

**Category**

Treatment - Drugs

#### 2

**Description**

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

**Category**

Treatment - Drugs

## Recruitment centers

#### 1

**Recruitment center****Name of recruitment center**

Alavi Clinic

**Full name of responsible person**

Maryamalsadat Razavi

**Street address**

Holy Ayatollah Street, Ardabil

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## Sponsors / Funding sources

#### 1

**Sponsor****Name of organization / entity**

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**Full name of responsible person**

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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**

Ardabil 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

## Person responsible for updating data

### Contact

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**Full name of responsible person**

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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