

Clinical Trial Protocol

Iranian Registry of Clinical Trials

02 Jul 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 anyform 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

City

Ardabil

Province

Ardabil

Postal code

5613974156

Phone

+98 45 3324 8888

Email

alavi@arums.ac.ir

Sponsors / Funding sources

1

Sponsor**Name of organization / entity**

Ardabil University of Medical Sciences

Full name of responsible person

Maryamalsadat Razavi

Street address

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

City

Ardabil

Province

Ardabil

Postal code

5618985991

Phone

+98 45 3353 4776

Email

research@arums.ac.ir

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

Street address

Ghotbe Ravandi Boulevard, Kashan

City

Kashan

Province

Isfahan

Postal code

1771844351

Phone

+98 31 5546 3378

Email

asemi_z@kaums.ac.ir

Person responsible for scientific inquiries

Contact

Name of organization / entity

Kashan University of Medical Sciences

Full name of responsible person

Zatollah Asemi

Position

Nutrition PhD

Latest degree

Ph.D.

Other areas of specialty/work

Nutrition

Street address

Bolvare Ghotbe Ravandi, Kashan

City

Kashan

Province

Isfahan

Postal code

8115187159

Phone

+98 31 5546 3378

Fax**Email**

asemi_z@kaums.ac.ir

Web page address

Person responsible for updating data

Contact

Name of organization / entity

Kashan University of Medical Sciences

Full name of responsible person

Zatollah Asemi

Position

Nutrition PhD

Latest degree

Ph.D.

Other areas of specialty/work

Nutrition

Street address

Bolvare Ghotbe Ravandi, Kashan

City

Kashan

Province

Isfahan

Postal code

1771844351

Phone

+98 31 5546 3378

Fax**Email**

asemi_z@kaums.ac.ir

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