

Clinical Trial Protocol

Iranian Registry of Clinical Trials

17 Sep 2026

Selenium supplementation effects on serum asymmetric dimethylarginine (ADMA) ,free androgen index (FAI) and visceral adiposity index (VAI) in women with polycystic ovary syndrome ; randomized clinical trial

Protocol summary

Summary

The study is a randomized, placebo-controlled, double blinded trial on pcos patients which is designed to examine the effects of selenium supplementaion on serum asymmetric dimethylarginine , free androgen index and visceral adiposity index in them.A total of 64 PCOs patients are selected by using Rotterdam criteria for PCOs (2003) and inclusion and exclusion criteria. Subjects are randomly divided to 2 groups. The first group receives selenium supplement; the second group receives placebo, each for 3 months. Process including: Collection of the blood samples (12 h fasting state), measurement of the serum ADMA, Apo A , APO B level before and after treatment. Measurement of lipid profile [total cholesterol, HDL-C, LDL-C and triglyceride (TG)], Hormonal parameters [total testosterone,SHBG], fasting plasma insulin levels, fasting plasma glucose levels and insulin resistance (according to HOMA).

General information

Acronym

IRCT registration information

IRCT registration number: **IRCT2014110519813N1**
Registration date: **2014-12-08, 1393/09/17**
Registration timing: **registered_while_recruiting**

Last update:

Update count: **0**

Registration date

2014-12-08, 1393/09/17

Registrant information

Name

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Name of organization / entity

Tehran University Of Medical Sceinces

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Recruitment status

Recruitment complete

Funding source

Tehran University of Medical Sciences

Expected recruitment start date

2014-11-22, 1393/09/01

Expected recruitment end date

2015-06-28, 1394/04/07

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Selenium supplementation effects on serum asymmetric dimethylarginine (ADMA) ,free androgen index (FAI) and visceral adiposity index (VAI) in women with polycystic ovary syndrome ; randomized clinical trial

Public title

Selenium supplementation effects on polycystic ovarian syndrome

Purpose

Prevention

Inclusion/Exclusion criteria

The inclusion criteria are as follows: women between 18 and 45 years old; diagnosed PCOS based on the Rotterdam criteria; non smokers the exclusion criteria are : having an androgen-secreting tumor, Cushing syndrome, congenital adrenal hyperplasia,

hyperprolactinemia, and/or virilism; impaired fasting glucose; diabetes, hypothyroidism; hyperthyroidism; liver disease; renal dysfunction; cardiovascular disease or dysfunction; pregnancy or breast feeding; taking medications known to affect metabolic parameters, such as corticosteroid drugs, ocp, selenium or multivitamin and mineral supplements -

Age

From **18 years** old to **45 years** old

Gender

Female

Phase

N/A

Groups that have been masked

No information

Sample size

Target sample size: **64**

Randomization (investigator's opinion)

Randomized

Randomization description

Blinding (investigator's opinion)

Double blinded

Blinding description

Placebo

Used

Assignment

Parallel

Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee

Tehran University Of Medical Sciences

Street address

Qods Ave. Keshavarz Blvd

City

Tehran

Postal code

Approval date

2014-10-21, 1393/07/29

Ethics committee reference number

1911/130/93/3

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

ADMA

Timepoint

before - after 3 month treatment

Method of measurement

by elisa kit

2

Description

serum cholesterol

Timepoint

before - after 3 month treatment

Method of measurement

kit

3

Description

fasting blood sugar

Timepoint

before - after 3 month treatment

Method of measurement

turbidimetry

4

Description

serum triglyceride

Timepoint

before - after 3 month treatment

Method of measurement

kit

5

Description

HDL

Timepoint

before - after 3 month treatment

Method of measurement

kit

6

Description

LDL

Timepoint

before - after 3 month treatment

Method of measurement

friedewald equation

7

Description

APO AI

Timepoint

before - after 3 month treatment

Method of measurement

kit

8

Description

APO B100

Timepoint

before - after 3 month treatment

Method of measurement

kit

9

Description

fasting serum insulin level

Timepoint

before - after 3 month treatment

Method of measurement

kit

10

Description

testosterone

Timepoint

before - after 3 month treatment

Method of measurement

kit

11

Description

SHBG

Timepoint

before - after 3 month treatment

Method of measurement

kit

12

Description

weight

Timepoint

before - after 3 month treatment

Method of measurement

scale

13

Description

waist circumference

Timepoint

before - after 3 month treatment

Method of measurement

Centimeter

14

Description

hip circumference

Timepoint

before - after 3 month treatment

Method of measurement

Centimeter

Secondary outcomes

empty

Intervention groups

1

Description

selenium, 200 microgram capsul, once a day for 3 month

Category

Treatment - Drugs

2

Description

placebo, once a day for 3 month

Category

Placebo

Recruitment centers

1

Recruitment center

Name of recruitment center

VALI-e-ASR Reproductive Health Research Center

Full name of responsible person

Mrs Hagholahi

Street address

Imam Khomeini Hospital Complex ,Keshavarz Blvd

City

Tehran

Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Tehran University Of Medical Sciences

Full name of responsible person

Dr Masoud Younesian

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Sixth Floor-Central University,Qods St., Keshavarz Blvd,tehran

City

Tehran

Grant name

Grant code / Reference number

Is the source of funding the same sponsor organization/entity?

Yes

Title of funding source

Tehran University Of Medical Sciences

Proportion provided by this source

100

Public or private sector

empty

Domestic or foreign origin

empty

Category of foreign source of funding

empty
Country of origin
Type of organization providing the funding
empty

Person responsible for general inquiries

Contact

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Sharing plan

Deidentified Individual Participant Data Set (IPD)
empty
Study Protocol
empty
Statistical Analysis Plan
empty
Informed Consent Form
empty
Clinical Study Report
empty
Analytic Code
empty
Data Dictionary
empty