Clinical Trial Protocol
Iranian Registry of Clinical Trials

11 Jul 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

Fatemeh Mohammad Hosseinzade

Name of organization / entity

Tehran University Of Medical Sceinces

Country

Iran (Islamic Republic of)

Phone

+98 21 8899 3059

Email address

fmhosseinzade@gmail.com

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 exclution 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 breas 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/د

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
torbidmetry

4

Description
serum triglyseride

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
weihgt
Timepoint
before - after 3 month treatment
Method of measurement
scale

13

Description
waist cicumfrence
Timepoint
before - after 3 month treatment
Method of measurement
Centimeter

14

Description
hip circumfernce
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
Street address
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

Name of organization / entity

Tehran University Of Medical Sciences

Full name of responsible person

Fatemeh Mohammad Hosseinzadeh

Position

MS student of nutrition

Other areas of specialty/work

Street address

Nutrition and Diet therapy School, Naderi Ave, Keshavarz Blvd.

City

Tehran

Postal code

Phone

+98 21 8895 1395

Fax

Email

fmhosseinzade@gmail.com

Web page address

Person responsible for scientific inquiries

Contact

Name of organization / entity

Tehran University of Medical Sciences

Full name of responsible person

Dr. Mohammad Javad Hosseinzadeh-Attar

Position

Assosiate professor

Other areas of specialty/work

Street address

Nutrition and Diet therapy School of Tehran University of Medical Sciences

City

Tehran

Postal code

Phone

+98 21 8895 1395

Fax

Email

hosseinzadeh.mdphd@yahoo.com

Web page address

Person responsible for updating data

Contact

Name of organization / entity

Tehran University of Medical Sciences

Full name of responsible person

Fatemeh Mohammad Hosseinzadeh

Position

MS student of nutrition

Other areas of specialty/work

Street address

Nutrition School of Tehran University of Medical Sciences

City

Tehran

Postal code

Phone

+98 21 8895 1395

Fax

Email

fmhosseinzade@gmail.com

Web page address

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