Clinical Trial Protocol
Iranian Registry of Clinical Trials

11 Jun 2026

The Effect of Selenium Supplementation on Glucose Homeostasis and Lipid Profile in Women with Metabolic Syndrome

Protocol summary

Study aim

Effect of selenium supplementation on glucose homeostasis and lipid profile in women with metabolic syndrome

Design

In this study, 70 women with metabolic syndrome referred to comprehensive health care centers in Kiar city were randomly divided into two groups: selenium and placebo

Settings and conduct

This double-blind clinical trial was conducted at the Kyar County Comprehensive Health Service Center. At first, the demographic questionnaire was filled out and the patients were asked to go to the laboratory for blood tests and then the necessary tests were taken.

Participants/Inclusion and exclusion criteria

Those with metabolic syndrome were chosen who had three of the following criteria to be diagnosed as metabolic syndrome: abnormal fasting blood glucose (equal to or greater than 110 mg/dl), dyslipidemia (triglyceride greater than or equal to 150 mg/dl or HDL cholesterol less than 50 mg/dl), and abdominal obesity (waist circumference in women > 88 cm), based on the indices presented in ATP III. The inclusion criteria were no consumption of antioxidant supplements, no underlying diseases including kidney diseases, hypothyroidism, digestive diseases, dyspepsia, etc., not being in menopause, not having weight loss diet over the last six months, not taking any drugs affecting the level of blood lipids, no pregnancy and breast-feeding. On the other hand, no willingness to continue the cooperation, pregnancy, not adhering to the study protocol, developing special diseases during the study were among the exclusion criteria. Note that patients taking insulin were also excluded.

Intervention groups

In the present study, the intervention group received 200 microgram selenium capsule and the placebo group received dextrose capsule in the same form and color.

Main outcome variables

FBS , Insulin,HOMA-IR, QUICKI, TRIGLYCERID, HDL cholestrol, LDL cholestrol, total cholestrol

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20191109045372N1**
Registration date: **2019-12-10, 1398/09/19**
Registration timing: **retrospective**

Last update: **2019-12-10, 1398/09/19**
Update count: **0**

Registration date

2019-12-10, 1398/09/19

Registrant information

Name

zeinab malekpour shahraki

Name of organization / entity

Country

Iran (Islamic Republic of)

Phone

+98 31 3792 3151

Email address

malekpour.z@skums.ac.ir

Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2017-12-22, 1396/10/01

Expected recruitment end date

2018-04-03, 1397/01/14

Actual recruitment start date

2017-12-21, 1396/09/30

Actual recruitment end date

2018-06-21, 1397/03/31

Trial completion date

2019-03-20, 1397/12/29

Scientific title

The Effect of Selenium Supplementation on Glucose Homeostasis and Lipid Profile in Women with Metabolic Syndrome

Public title

Selenium in metabolic syndrome

Purpose

Prevention

Inclusion/Exclusion criteria

Inclusion criteria:

Were no consumption of antioxidant supplements NO underlying diseases including kidney diseases, hypothyroidism, digestive diseases, dyspepsia, etc. Not being in menopause Not having weight loss diet over the last six months Not taking any drugs affecting the level of blood lipids No pregnancy and breast-feeding

Exclusion criteria:

No willingness to continue the cooperation, pregnancy, not adhering to the study protocol, developing special diseases during the study were among the exclusion criteria. Note that patients taking insulin were also excluded.

Age

From **20 years** old to **49 years** old

Gender

Female

Phase

3

Groups that have been masked

- Participant
- Care provider
- Investigator
- Outcome assessor

Sample size

Target sample size: **70**

Actual sample size reached: **66**

Randomization (investigator's opinion)

Randomized

Randomization description

The subjects were categorized into selenium and placebo groups as two random block designs. In the selenium group, 200 mcg selenium capsule while in the placebo group, a placebo capsule which was identical to selenium in terms of color and appearance were given to the subjects for 8 weeks.

Blinding (investigator's opinion)

Double blinded

Blinding description

In this study, patients and people who will do the tests will not know if they are taking selenium or placebo, and only the researcher and data analyzer will know how to blind.

Placebo

Used

Assignment

Parallel

Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee

EthicsCommittee of Isfahan University of Medical Sciences

Street address

Hezargarib Street

City

Isfahan

Province

Isfehan

Postal code

73461-81746

Approval date

2017-08-19, 1396/05/28

Ethics committee reference number

IR.MUI.REC.1396.348

Health conditions studied

1

Description of health condition studied

METABOLIC SYNDROME

ICD-10 code

E88.81

ICD-10 code description

Metabolic syndrome

Primary outcomes

1

Description

FBS

Timepoint

The beginning of the study and the end of the study

Method of measurement

Biochemical

2

Description

Insulin

Timepoint

The beginning of the study and the end of the study

Method of measurement

Eliza

3

Description

HOMA-IR

Timepoint
The beginning of the study and the end of the study
Method of measurement
FORMULA

4

Description
QUICKI
Timepoint
The beginning of the study and the end of the study
Method of measurement
FORMULA

5

Description
TRIGLYCERIDE
Timepoint
The beginning of the study and the end of the study
Method of measurement
BIOCHEMICAL

6

Description
Total cholestrol
Timepoint
The beginning of the study and the end of the study
Method of measurement
Biochemical

7

Description
HDL cholestrol
Timepoint
The beginning of the study and the end of the study
Method of measurement
BIOCHEMICAL

8

Description
LDL cholestrol
Timepoint
The beginning of the study and the end of the study
Method of measurement
Formula

Secondary outcomes

1

Description
Body Mass Index
Timepoint
The beginning and the end of the study
Method of measurement
Weight (kg) / Height (m) to power 2

Intervention groups

1

Description
Intervention group: Thirty-five patients were included in the intervention group.Participants were delivered a 200 microgram selenium capsule made by 21st Century America Inc. purchased from Pourtab Tehran.Participants were given the capsule for 8 weeks. Each person consumes one selenium capsule daily.
Category
Prevention

2

Description
Control group: Thirty-five subjects were included in the control group.In the control group, a placebo containing 200 µg dextrose was not significantly different in appearance and color from selenium. Subjects in the placebo group consumed one placebo capsule daily for 8 weeks.The placebo was manufactured by the Faculty of Pharmacy of Isfahan University of Medical Sciences
Category
Placebo

Recruitment centers

1

Recruitment center
Name of recruitment center
مراکز خدمات جامع سلامت بخش مرکزی شهرستان کیار
Full name of responsible person
Mohammad Hasan Entezari.
Street address
Hezargarib street
City
Isfahan
Province
Isfehan
Postal code
73461-81746
Phone
+98 31 3792 3151
Email
entezari@hlth.mui.ac.ir

Sponsors / Funding sources

1

Sponsor
Name of organization / entity
Esfahan University of Medical Sciences
Full name of responsible person
: Mohammad Hasan Entezari
Street address
Hezargarib Street
City
Isfahan

Province
Isfehan
Postal code
73461-81746
Phone
+98 31 3792 3151
Email
entezari@hlth.mui.ac.ir

Grant name

Grant code / Reference number

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

Title of funding source
Esfahan 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
Esfahan University of Medical Sciences
Full name of responsible person
Zeinab Malekpour Shahraki
Position
Student
Latest degree
Bachelor
Other areas of specialty/work
Nutrition
Street address
Hezargarib Street
City
Isfahan
Province
Isfehan
Postal code
73461-81746
Phone
+98 31 3792 3151
Email
msz_nut@yahoo.com

Person responsible for scientific inquiries

Contact

Name of organization / entity
Esfahan University of Medical Sciences
Full name of responsible person
Mohammad Hasan Entezari
Position
Associate Professor
Latest degree
Ph.D.
Other areas of specialty/work
Nutrition
Street address
Hezargarib Street
City
Isfahan
Province
Isfehan
Postal code
73461-81746
Phone
+98 31 3792 3151
Email
entezari@hlth.mui.ac.ir

Person responsible for updating data

Contact

Name of organization / entity
Esfahan University of Medical Sciences
Full name of responsible person
Zeinab Malekpour Shahraki
Position
Masters student
Latest degree
Bachelor
Other areas of specialty/work
Nutrition
Street address
Hezargarib Street
City
Isfahan
Province
Isfehan
Postal code
73461-81746
Phone
+98 31 3792 3151
Email
msz_nut@yahoo.com

Sharing plan

Deidentified Individual Participant Data Set (IPD)
Yes - There is a plan to make this available
Study Protocol
Yes - There is a plan to make this available
Statistical Analysis Plan
Yes - There is a plan to make this available
Informed Consent Form
Yes - There is a plan to make this available
Clinical Study Report
Yes - There is 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

Title and more details about the data/document

Information on major and minor consequences will be shared.

When the data will become available and for how long

One year after publishing the documentation

To whom data/document is available

Anyone working in this field can apply for documentation.

Under which criteria data/document could be used

People can access the documentation via email.

From where data/document is obtainable

People can access the documentation via email.

What processes are involved for a request to access data/document

People can access the desired documentation in a file if they email the person in charge.

Comments