

Clinical Trial Protocol

Iranian Registry of Clinical Trials

01 Jul 2026

The effect of selenium supplementation on regression and metabolic profiles in women with cervical intraepithelial neoplasia 1(CIN1)

Protocol summary

Study aim

The aim of this study is to determine the effects of selenium supplementation on regression and metabolic profiles in women with cervical intraepithelial neoplasia 1(CIN1)

Design

In this randomized double-blind placebo-controlled trial, patients will be assigned into two groups to receive selenium supplements or placebo.

Settings and conduct

56 women with CIN1 eligible and referred to Kossar Clinic affiliated to Arak University of Medical Sciences, Arak, Iran in the study will be selected.

Participants/Inclusion and exclusion criteria

Patients aged between 18 and 55 years with CIN1 will be included. The exclusion criteria will be as follows: women who had a history of cervical cancer or other cancers of the lower genital tract, a history of hysterectomy or destructive therapy of the cervix and pregnant women.

Intervention groups

Patients will be assigned to receive either 200 µg selenium supplement (intervention group: n=28) or placebo (control group: n=28).

Main outcome variables

Fasting blood samples will be taken at baseline and after 6 months of intervention to measure metabolic profiles. Baseline and End-of-trial fasting plasma glucose (FPG), serum insulin, lipid profiles and hs-CRP levels.

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT201412215623N32**

Registration date: **2015-01-06, 1393/10/16**

Registration timing: **retrospective**

Last update: **2019-09-11, 1398/06/20**

Update count: **1**

Registration date

2015-01-06, 1393/10/16

Registrant information

Name

Zatollah Asemi

Name of organization / entity

Kashan University of Medical Sciences

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Iran (Islamic Republic of)

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Recruitment status

Recruitment complete

Funding source

Arak University of Medical Sciences

Expected recruitment start date

2014-03-18, 1392/12/27

Expected recruitment end date

2014-08-10, 1393/05/19

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

The effect of selenium supplementation on regression and metabolic profiles in women with cervical intraepithelial neoplasia 1(CIN1)

Public title

Effect of supplementation in regression of cervical intraepithelial neoplasia 1

Purpose

Treatment

Inclusion/Exclusion criteria

Inclusion criteria:
Women aged 18-55 years; diagnosed with cervical intraepithelial neoplasia 1

Exclusion criteria:
Women who had a history of cervical cancer or other cancers of the lower genital tract History of hysterectomy or destructive therapy of the cervix
Pregnant women

Age
From **18 years** old to **55 years** old

Gender
Female

Phase
3

Groups that have been masked

- Participant
- Investigator
- Outcome assessor

Sample size
Target sample size: **56**

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 either selenium supplements (n = 28) or placebo (n = 28). Randomization will be done by the use of computer-generated random numbers.

Blinding (investigator's opinion)
Double blinded

Blinding description
Randomization and allocation will be concealed from the researchers and participants until the final analyses are completed. Another person at the Oncology Clinic at the Arak University of Medical Sciences, who is not involved in the trial and not aware of random sequences, will be assigned the participants to the numbered bottles of capsules.

Placebo
Used

Assignment
Parallel

Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee

Arak University of Medical Sciences

Street address

Vice-chancellor for Education and Research, Sardasht

Avenue, Arak

City
Arak

Province
Markazi

Postal code
3848176941

Approval date
2014-03-17, 1392/12/26

Ethics committee reference number
92-160-6

Health conditions studied

1

Description of health condition studied

Cervical intraepithelial neoplasia 1(CIN1)

ICD-10 code

C53

ICD-10 code description

Malignant neoplasm of cervix uteri

Primary outcomes

1

Description

Cervical intraepithelial neoplasia grade 1

Timepoint

Baseline and End-of-trial

Method of measurement

Colposcopy

Secondary outcomes

1

Description

Insulin

Timepoint

Baseline and End-of-trial

Method of measurement

Elisa kit

2

Description

Insulin resistance

Timepoint

Baseline and End-of-trial

Method of measurement

Calculation using HOMA formula

3

Description

Total cholesterol

Timepoint

Baseline and End-of-trial

Method of measurement

Enzymatic kit

4

Description

Triglycerides

Timepoint

Baseline and End-of-trial

Method of measurement

Enzymatic kit

5

Description

HDL

Timepoint

Baseline and End-of-trial

Method of measurement

Enzymatic kit

6

Description

High-sensitivity C-reactive Protein

Timepoint

Baseline and End-of-trial

Method of measurement

Elisa kit

7

Description

Nitric oxide

Timepoint

Baseline and End-of-trial

Method of measurement

Spectrophotometry

8

Description

Glutathione

Timepoint

Baseline and End-of-trial

Method of measurement

Spectrophotometry

9

Description

Total antioxidant capacity

Timepoint

Baseline and End-of-trial

Method of measurement

Spectrophotometry

10

Description

Malondialdehyde

Timepoint

Baseline and End-of-trial

Method of measurement

Spectrophotometry

11

Description

Fasting blood sugar

Timepoint

Baseline and End-of-trial

Method of measurement

Enzymatic kit

Intervention groups

1

Description

Control group: Placebo tablet, daily, for 6 months orally.

Category

Treatment - Drugs

2

Description

Intervention group: Selenium tablet, 200 µg, daily, for 6 months orally.

Category

Treatment - Drugs

Recruitment centers

1

Recruitment center

Name of recruitment center

Kossar Clinic

Full name of responsible person

Maryam Karamali

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Imam Khomeini street, Arak

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Sponsors / Funding sources

1

Sponsor

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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
Arak 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
Nutritionist
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Person responsible for updating data

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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