

# 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

###### Country

Iran (Islamic Republic of)

###### Phone

+98 36 1534 3570

###### Email address

asemi\_z@kaums.ac.ir

##### 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

##### **Street address**

Imam Khomeini street, Arak

##### **City**

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##### **Postal code**

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it.kousar@arakmu.ac.ir

## **Sponsors / Funding sources**

### 1

#### **Sponsor**

##### **Name of organization / entity**

Arak University of Medical Sciences

##### **Full name of responsible person**

Maryam Karamali

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Vice-chancellor for Education and Research, Sardasht Avenue, Arak

##### **City**

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research@arakmu.ac.ir

**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

**Latest degree**

Ph.D.

**Other areas of specialty/work**

Nutrition

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**Full name of responsible person**

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**Position**

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Nutrition

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**Web page address****Person responsible for updating data****Contact****Name of organization / entity**

Kashan University of Medical Sciences

**Full name of responsible person**

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**Fax****Email**

asemi\_r@yahoo.com

**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