

# Clinical Trial Protocol

## Iranian Registry of Clinical Trials

10 Jun 2026

### Clinical trial of the effect of vitamin D supplementation compared with the placebo on recurrence and metabolic profiles in women with cervical intraepithelial neoplasia 2 and 3

#### Protocol summary

##### Study aim

Objective: The aim of this study is to determine the effects of vitamin D supplementation on recurrence and metabolic profiles in women with cervical intraepithelial neoplasia 2 and 3.

##### Design

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

##### Settings and conduct

58 women with CIN2-3 eligible and referred to Oncology Clinic affiliated to Kashan University of Medical Sciences, Kashan, Iran in the study will be selected.

##### Participants/Inclusion and exclusion criteria

Patients aged between 25 and 65 years with CIN2-3 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 50000 IU vitamin D supplement every 2 weeks (intervention group: n=29) or placebo (control group: n=29).

##### 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: **IRCT201601045623N65**  
Registration date: **2016-01-04, 1394/10/14**

Registration timing: **registered\_while\_recruiting**

Last update: **2019-09-23, 1398/07/01**

Update count: **1**

##### Registration date

2016-01-04, 1394/10/14

##### 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

Vice chancellor for research, Kashan University of Medical Sciences

##### Expected recruitment start date

2015-12-22, 1394/10/01

##### Expected recruitment end date

2016-02-20, 1394/12/01

##### Actual recruitment start date

empty

##### Actual recruitment end date

empty

##### Trial completion date

empty

##### Scientific title

Clinical trial of the effect of vitamin D supplementation compared with the placebo on recurrence and metabolic

profiles in women with cervical intraepithelial neoplasia 2 and 3

#### Public title

Effect of supplementation in treatment of women with cervical intraepithelial neoplasia 2 and 3

#### Purpose

Treatment

#### Inclusion/Exclusion criteria

##### Inclusion criteria:

Women with cervical intraepithelial neoplasia 2 and 3  
Aged 25 to 65 years old

##### 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 **25 years** old to **65 years** old

#### Gender

Female

#### Phase

3

#### Groups that have been masked

- Participant
- Investigator
- Outcome assessor

#### Sample size

Target sample size: **58**

#### Randomization (investigator's opinion)

Randomized

#### Randomization description

t study baseline and after stratification for pre-intervention BMI and age, subjects will be randomly divided into two groups to take either vitamin D supplements (n = 29) or placebo (n = 29). 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 Kashan 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

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 Kashan 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.

## Secondary Ids

empty

## Ethics committees

### 1

#### Ethics committee

##### Name of ethics committee

Ethics committee of Kashan University of Medical Sciences

##### Street address

Ghotbe Ravandi Boulevard, Kashan

##### City

Kashan

##### Province

Isfahan

##### Postal code

8115187159

#### Approval date

2015-12-22, 1394/10/01

#### Ethics committee reference number

IR.Kaums.REC.1394.129

## Health conditions studied

### 1

#### Description of health condition studied

Cervical intraepithelial neoplasia 2 and 3

#### ICD-10 code

C53.9

#### ICD-10 code description

Cervix uteri, unspecified

## Primary outcomes

### 1

#### Description

Recurrence

#### Timepoint

Six months after intervention

#### Method of measurement

Colposcopy

## Secondary outcomes

### 1

#### Description

Insulin

#### Timepoint

At the beginning of the study and after 6 months of intervention

#### Method of measurement

Elisa kit

### 2

#### Description

Nitric oxide  
**Timepoint**  
At the beginning of the study and after 6 months of intervention  
**Method of measurement**  
Spectrophotometry

### 3

**Description**  
hs-CRP  
**Timepoint**  
At the beginning of the study and after 6 months of intervention  
**Method of measurement**  
Elisa kit

### 4

**Description**  
Triglycerides  
**Timepoint**  
At the beginning of the study and after 6 months of intervention  
**Method of measurement**  
Enzymatic kit

### 5

**Description**  
Cholesterol  
**Timepoint**  
At the beginning of the study and after 6 months of intervention  
**Method of measurement**  
Enzymatic kit

### 6

**Description**  
Total antioxidant  
**Timepoint**  
At the beginning of the study and after 6 months of intervention  
**Method of measurement**  
Spectrophotometry

### 7

**Description**  
Malondialdehyde  
**Timepoint**  
At the beginning of the study and after 6 months of intervention  
**Method of measurement**  
Spectrophotometry

### 8

**Description**  
Fasting blood sugar  
**Timepoint**  
At the beginning of the study and after 6 months of

intervention  
**Method of measurement**  
Baseline and End-of-trial

### 9

**Description**  
Serum vitamin D  
**Timepoint**  
At the beginning of the study and after 6 months of intervention  
**Method of measurement**  
Elisa kit

### 10

**Description**  
HDL  
**Timepoint**  
At the beginning of the study and after 6 months of intervention  
**Method of measurement**  
Enzymatic kit

### 11

**Description**  
Insulin resistance  
**Timepoint**  
At the beginning of the study and after 6 months of intervention  
**Method of measurement**  
Calculation using HOMA formula

## **Intervention groups**

### 1

**Description**  
Intervention group: Vitamin D supplement, 50000 IU, every 2 weeks, for 6 months orally.  
**Category**  
Treatment - Drugs

### 2

**Description**  
Control group: Placebo, every 2 weeks, for 6 months orally.  
**Category**  
Placebo

## **Recruitment centers**

### 1

**Recruitment center**  
**Name of recruitment center**  
Naghavi oncology Clinic  
**Full name of responsible person**  
Zatollah Asemi  
**Street address**

Ghotbe Ravandi Boulevard, Kashan

**City**

Kashan

**Province**

Isfahan

**Postal code**

8115187159

**Phone**

+98 31 5546 3378

**Email**

asemi\_r@yahoo.com

## Sponsors / Funding sources

### 1

#### Sponsor

**Name of organization / entity**

Vice chancellor for research, Kashan University of Medical Sciences

**Full name of responsible person**

Gholamali Hamidi

**Street address**

Ghotbe Ravandi Boulevard, Kashan

**City**

Kashan

**Province**

Isfahan

**Postal code**

8115187159

**Phone**

+98 31 5546 3378

**Email**

hamidi-gh@kaums.ac.ir

**Grant name**

**Grant code / Reference number**

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

Yes

**Title of funding source**

Vice chancellor for research, Kashan 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**

Associate professor

**Latest degree**

Ph.D.

**Other areas of specialty/work**

Nutrition

**Street address**

Bolvare Ghotbe Ravandi, Kashan

**City**

Kashan

**Province**

Isfahan

**Postal code**

8115187159

**Phone**

+98 31 5546 3378

**Email**

asemi\_r@yahoo.com

## Person responsible for scientific inquiries

#### Contact

**Name of organization / entity**

Kashan University of Medical Sciences

**Full name of responsible person**

Zatollah Asemi

**Position**

PhD of Nutrition

**Latest degree**

Ph.D.

**Other areas of specialty/work**

Nutrition

**Street address**

Ghotbe Ravandi Boulevard, Kashan

**City**

Kashan

**Province**

Isfahan

**Postal code**

8115187159

**Phone**

+98 31 5546 3378

**Fax**

**Email**

asemi\_r@yahoo.com

**Web page address**

## Person responsible for updating data

#### Contact

**Name of organization / entity**

Kashan University of Medical Sciences

**Full name of responsible person**

Zatollah Asemi

**Position**

PhD of Nutrition

**Latest degree**

Ph.D.

**Other areas of specialty/work**

Nutrition

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Ghotbe Ravandi Boulevard, Kashan

**City**

Kashan

**Province**

Isfahan

**Postal code**

8115187159

**Phone**

+98 31 5546 3378

**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