

# Clinical Trial Protocol

## Iranian Registry of Clinical Trials

14 Jul 2026

### The effect of vitamin D supplementation on treatment, metabolic profiles and hs-CRP in women with cervical intraepithelial neoplasia 1(CIN1)

#### Protocol summary

##### Study aim

Objective: The aim of this study is to determine the effects of vitamin D supplementation on treatment, metabolic profiles and hs-CRP 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 vitamin D supplements or placebo.

##### Settings and conduct

58 women with cervical intraepithelial neoplasia 1 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 18 and 55 years with cervical intraepithelial neoplasia 1 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

Intervention group: Vitamin D pearl, 50000 IU (Zahravi, Tabriz, Iran), every 2 weeks, for 6 months orally. Control group: Placebo pearl (Barij Essence, Kashan, Iran), every 2 weeks, for 6 months orally.

##### Main outcome variables

Fasting plasma glucose (FPG), serum levels of insulin, lipid profiles and hs-CRP.

#### General information

##### Reason for update

Due to an error, the request for an update in our website has been conducted after paper published. However, the revisions were in accordance with either the original approved proposal or with coordination with Vice Chancellor of Research at the University.

##### Acronym

#### IRCT registration information

IRCT registration number: **IRCT201412065623N30**

Registration date: **2014-12-19, 1393/09/28**

Registration timing: **retrospective**

Last update: **2019-10-30, 1398/08/08**

Update count: **1**

##### Registration date

2014-12-19, 1393/09/28

#### 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

Kashan University of Medical Sciences

#### Expected recruitment start date

2014-08-06, 1393/05/15

#### Expected recruitment end date

2014-08-27, 1393/06/05

#### Actual recruitment start date

empty

#### Actual recruitment end date

empty

#### Trial completion date

empty

#### Scientific title

The effect of vitamin D supplementation on treatment, metabolic profiles and hs-CRP in women with cervical

intraepithelial neoplasia 1(CIN1)

#### Public title

Effect of supplementation in treatment 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: **58**

#### Randomization (investigator's opinion)

Randomized

#### Randomization description

At study baseline and after stratification for pre-intervention BMI and age, participants in each block will be randomly allocated into two treatment groups to take either vitamin D supplements (n = 29) or placebo (n = 29). Randomization will be done by the use of Stat Trek software. Participants, investigators or the assessors of the outcomes are also unaware of the study groups. <https://stattrek.com/statistics/random-number-generator.aspx>

#### 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 Naghavi outpatient Clinic who is not involved in the trial and not aware of random sequences will allocate the numbered bottles of capsules to participants. Supplements and placebo are in the same packaging at the Barij Essence pharmaceutical company. Only the code is written on the packages. Patients and researcher do not know the type of drug and after analyzing the data, packet codes are decoded.

#### Placebo

Used

#### Assignment

Parallel

#### Other design features

## Secondary Ids

empty

## Ethics committees

### 1

#### Ethics committee

##### Name of ethics committee

Kashan University of Medical Sciences

##### Street address

Bolvare Ghotbe Ravandi, Kashan

##### City

Kashan

##### Province

Isfahan

##### Postal code

8115187159

#### Approval date

2014-08-05, 1393/05/14

#### Ethics committee reference number

29/5/1/4229/پ

## Health conditions studied

### 1

#### Description of health condition studied

Cervical intraepithelial neoplasia 1(CIN1)

#### ICD-10 code

C53.9

#### ICD-10 code description

Cervix uteri, unspecified

## Primary outcomes

### 1

#### Description

Cervical intraepithelial neoplasia grade

#### Timepoint

Baseline and End-of-trial

#### Method of measurement

Colposcopic

## 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

### 12

**Description**  
Serum vitamin D  
**Timepoint**  
Baseline and End-of-trial  
**Method of measurement**  
Elisa kit

## Intervention groups

### 1

**Description**  
Intervention group: Vitamin D pearl, 50000 IU (Zahravi, Tabriz, Iran), every 2 weeks, for 6 months orally.  
**Category**  
Treatment - Drugs

### 2

**Description**  
Control group: Placebo pearl (Barij Essence, Kashan, Iran), every 2 weeks, for 6 months orally.  
**Category**  
Treatment - Drugs

## Recruitment centers

### 1

**Recruitment center**  
**Name of recruitment center**  
Naghavi outpatient Clinic  
**Full name of responsible person**  
Zatollah Asemi  
**Street address**  
Shahid Rajaee Avenue, Kashan  
**City**  
Kashan  
**Province**

Isfahan  
**Postal code**  
8115187159  
**Phone**  
+98 31 5546 3378  
**Email**  
asemi\_r@yahoo.com

Bolvare Ghotbe Ravandi, 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**  
Kashan University of Medical Sciences  
**Full name of responsible person**  
Gholamali Hamidi  
**Street address**  
Bolvare Ghotbe Ravandi, 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**  
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**

## Person responsible for scientific inquiries

#### Contact

**Name of organization / entity**  
Kashan University of Medical Sciences  
**Full name of responsible person**  
Zatollah Asemi  
**Position**  
Nutrition PhD  
**Latest degree**  
Ph.D.  
**Other areas of specialty/work**  
Nutrition  
**Street address**  
Research Center for Biochemistry and Nutrition in Metabolic Diseases, Kashan University of Medical Sciences, Kashan, I.R. Iran  
**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**  
Nutrition PhD  
**Latest degree**  
Ph.D.  
**Other areas of specialty/work**  
Nutrition  
**Street address**  
Bolvare Ghotbe Ravandi, Kashan  
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**Province**  
Isfahan

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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