Clinical Trial Protocol
Iranian Registry of Clinical Trials

17 Sep 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 1will 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
Isfehan
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

Isfehan
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
Isfehan
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
Bolvare Ghotbe Ravandi, Kashan
City
Kashan
Province
Isfehan
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
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
Isfehan
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
City
Kashan
Province
Isfehan

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