Clinical Trial Protocol
Iranian Registry of Clinical Trials

22 Nov 2026

The effect of oral Vitamin D3 supplementation on cardiovascular risk factors in post-menopausal women in Gorgan

Protocol summary

Summary
120 healthy non surgical postmenopausal women without serious diseases such as cardiovascular , diabetes mellitus with vitamin D insufficiency (defined as a 25-[OH] D level < 75 nmol/L) were randomly assigned to receive placebo or vitamin D3 2000 IU once daily. The patients will assessed for fasting lipid profile, FBS, blood pressure, weight and BMI before and after 12 weeks of treatment. Data is analyzed using t-test.

General information

Acronym
IRCT registration information
IRCT registration number: **IRCT2012091810868N1**
Registration date: **2012-10-09, 1391/07/18**
Registration timing: **retrospective**

Last update:
Update count: **0**
Registration date
2012-10-09, 1391/07/18

Registrant information
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Recruitment status
Recruitment complete
Funding source
Golestan University of Medical Sciences

Expected recruitment start date
2010-04-21, 1389/02/01
Expected recruitment end date
2012-04-20, 1391/02/01
Actual recruitment start date
empty
Actual recruitment end date
empty
Trial completion date
empty

Scientific title
The effect of oral Vitamin D3 supplementation on cardiovascular risk factors in post-menopausal women in Gorgan

Public title
The effect of Vitamin D supplementation on serum cardiovascular biomarkers
Purpose
Prevention
Inclusion/Exclusion criteria
Inclusion criteria: Postmenopausal women; absent of any serious diagnosed illnesses such as cardiovascular; diabetus mellitus; taking medications such as anti-diabetes; anti-hypertensive and anti-lipidemic agents; hormone replacement therapy (HRT); vitamin D and or calcium –D supplementation and smoking. Exclusion criteria: using any medication which affect the outcome variables.
Age
From **45 years** old to **60 years** old
Gender
Female

Phase
N/A
Groups that have been masked
No information
Sample size
Target sample size: **120**

Randomization (investigator's opinion)
Randomized
Randomization description
Blinding (investigator's opinion)
Double blinded
Blinding description
Placebo
Used
Assignment
Parallel
Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee
Name of ethics committee
Golestan University of Medical Sciences
Street address
Golestan University of Medical Sciences
City
Gorgan
Postal code
49165-568
Approval date
2009-09-27, 1388/07/05
Ethics committee reference number
2135/35/پ/گ

Health conditions studied

1

Description of health condition studied
Cardiovascular
ICD-10 code
Y52.6
ICD-10 code description
Antihyperlipidaemic and antiarteriosclerotic drugs

Primary outcomes

1

Description
HDL
Timepoint
At baseline and after 12 weeks
Method of measurement
Serum

2

Description
Cholestrol
Timepoint
At baseline and after 12 weeks
Method of measurement
Serum

3

Description
LDL
Timepoint
At baseline and after 12 weeks
Method of measurement
Serum

4

Description
Triglyceride
Timepoint
At baseline and after 12 weeks
Method of measurement
serum

5

Description
FBS
Timepoint
At baseline and after 12 weeks
Method of measurement
Serum

6

Description
Blood Pressure
Timepoint
At baseline and after 12 weeks
Method of measurement
Serum

Secondary outcomes

empty

Intervention groups

1

Description
Oral pear of Vitamin D3 2000 IU daily for 12 weeks
Category
Treatment - Drugs

2

Description
Oral pearl placebo once daily for 12 weeks
Category
Placebo

Recruitment centers

1

Recruitment center
Name of recruitment center
Health centers in Gorgan
Full name of responsible person
Moghassemi Sedigheh
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Sponsors / Funding sources

1

Sponsor
Name of organization / entity
Golestan University Of Medical Sciences
Full name of responsible person
Dr Golalipoor MJ
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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
Golestan University Of Medical Sciences
Proportion provided by this source
100
Public or private sector
empty
Domestic or foreign origin
empty
Category of foreign source of funding
empty
Country of origin
Type of organization providing the funding
empty

Person responsible for general inquiries

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Sharing plan

Deidentified Individual Participant Data Set (IPD)
empty
Study Protocol
empty
Statistical Analysis Plan
empty
Informed Consent Form
empty

Clinical Study Report

empty

Analytic Code

empty

Data Dictionary

empty