

Clinical Trial Protocol

Iranian Registry of Clinical Trials

30 May 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

Name

Sedigheh Moghasemi

Name of organization / entity

Golestan university of Medical sciences

Country

Iran (Islamic Republic of)

Phone

+98 17 1443 0354

Email address

moghassemi@goums.ac.ir

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; diabetes 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

Street address

Golestan University of Medical Sciences

City

Gorgan

Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Golestan University Of Medical Sciences

Full name of responsible person

Dr Golalipoor MJ

Street address

Golestan University of Medical Sciences

City

Gorgan

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

Contact

Name of organization / entity

Golestan University of medical sciences

Full name of responsible person

Moghassemi Sedigheh

Position

MSc of Midwifery/ faculty member

Other areas of specialty/work

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Web page address

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