

Clinical Trial Protocol

Iranian Registry of Clinical Trials

26 Jul 2026

Effect of Calcium-vitamin D supplementation on serum lipids levels of 50-75 years old women

Protocol summary

Summary

In this randomized single-blind study without placebo control, the effect of calcium-vitamin D supplementation on serum lipid levels of 100 women 50-75 years old with cholesterol of 200-239 and triglyceride of 150-199 and LDL of 100-159 and vitamin D level less than 30 ng/mL will be investigated. In case of hyperlipidemia, diabetes, heart disease and thyroid diseases, patients are excluded. First, the patient's BMI and waist circumference are calculated. The patients are given Calcium-vitamin D supplement tablets made by Tehran shimi pharmaceutical manufacturing Co. twice-daily (containing 500 mg calcium and 200 IU vitamin D) before breakfast and before lunch for 6 months. Then, blood lipid levels will be recorded after 3 and 6 months. The patient's weight, height and waist circumference are recorded at the end of 6 months and compared with initial data.

General information

Acronym

IRCT registration information

IRCT registration number: **IRCT2017020532406N1**

Registration date: **2017-03-01, 1395/12/11**

Registration timing: **registered_while_recruiting**

Last update:

Update count: **0**

Registration date

2017-03-01, 1395/12/11

Registrant information

Name

Maryam Javadian Kootenaei

Name of organization / entity

Babol University of Medical Sciences

Country

Iran (Islamic Republic of)

Phone

+98 11 3334 2334

Email address

m.javadian@mubabol.ac.ir

Recruitment status

Recruitment complete

Funding source

Vice Chancellor for Research and Technology of Babol University of Medical Sciences

Expected recruitment start date

2016-03-20, 1395/01/01

Expected recruitment end date

2017-03-19, 1395/12/29

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Effect of Calcium-vitamin D supplementation on serum lipids levels of 50-75 years old women

Public title

Effect of Calcium-vitamin D supplementation on serum lipids levels of 50-75 years old women

Purpose

Treatment

Inclusion/Exclusion criteria

Inclusion criteria: Not using calcium-vitamin D supplementation, normal thyroid hormone levels, satisfaction for participating in study. Exclusion criteria: underlying disease such as hyperlipidemia, diabetes, heart disease, atorvastatin consumption

Age

From **50 years** old to **75 years** old

Gender

Female

Phase

2-3

Groups that have been masked

No information

Sample size

Target sample size: 100

Randomization (investigator's opinion)

N/A

Randomization description

Blinding (investigator's opinion)

Single blinded

Blinding description

Placebo

Not used

Assignment

Single

Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee

Ethics committee of Babol University of Medical sciences

Street address

Babol University of Medical sciences, Ganjafrooz Avenue

City

Babol

Postal code

Approval date

2016-10-31, 1395/08/10

Ethics committee reference number

MUBABOL.REC.1395.183

Health conditions studied

1

Description of health condition studied

Hyperlipidaemia

ICD-10 code

E78.5

ICD-10 code description

Hyperlipidaemia, unspecified

Primary outcomes

1

Description

HDL

Timepoint

Baseline

Method of measurement

mg/dL

2

Description

LDL

Timepoint

Baseline

Method of measurement

mg/dL

3

Description

TG

Timepoint

Baseline

Method of measurement

mg/dL

4

Description

25 Hydroxy vitamin D

Timepoint

Baseline

Method of measurement

ng/mL

5

Description

BMI

Timepoint

Baseline

Method of measurement

kg/m2

6

Description

waist circumference

Timepoint

Baseline

Method of measurement

cm

Secondary outcomes

empty

Intervention groups

1

Description

The patients are given Calcium-vitamin D supplement tablets made by Tehran shimi pharmaceutical manufacturing Co. twice-daily (containing 500 mg calcium and 200 IU vitamin D) before breakfast and before lunch for 6 months

Category

Treatment - Drugs

Recruitment centers

1

Recruitment center

Name of recruitment center

Obstetrics Clinic of Ayatollah Rouhani Hospital of Babol

Full name of responsible person

Maryam Javadian, MD

Street address

Ayatollah Rouhani Hospital, Ganjafroz avenue

City

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Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Vice Chancellor for Research and Technology, Babol University of Medical Sciences

Full name of responsible person

Ali Akbar Moghadamnia, MD

Street address

Vice Chancellor for Research and Technology, Babol University of Medical sciences, Gangafroz Avenue

City

Babol

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 and Technology, Babol 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

Babol University of Medical Sciences

Full name of responsible person

Maryam Javadian, MD

Position

Obstetrician

Other areas of specialty/work

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Roya Gharoei, MD

Position

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Other areas of specialty/work

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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