

Clinical Trial Protocol

Iranian Registry of Clinical Trials

28 Sep 2026

Effect of vitamin D supplementation on carotid intima-media thickness and risk factors of cardiovascular disease in patients with metabolic syndrome

Protocol summary

Summary

The aim of this study is to evaluate the possible effects of vitamin D supplementation on carotid intima-media thickness and risk factors of cardiovascular disease in patients with metabolic syndrome. To do this, 80 volunteers with metabolic syndrome and with the age of 30-50 years will be studied. This study will be double blinded (subjects and researchers). Subjects will be selected and assigned randomly to one of the two groups; intervention: 50000 IU vitamin D3 and placebo. Participants will be asked to take one supplement every week with lunch for 4 months. Dietary intake, exposure on sunlight, physical activity will be assessed in baseline, after 2 months and at the end of the study. At the first and last visits, carotid intima media thickness and inflammatory and metabolic factors, insulin, 25-OHD, parathyroid hormone and calcium will be measured.

General information

Acronym

IRCT registration information

IRCT registration number: **IRCT201409033140N14**

Registration date: **2014-10-27, 1393/08/05**

Registration timing: **prospective**

Last update:

Update count: **0**

Registration date

2014-10-27, 1393/08/05

Registrant information

Name

Bahram Pourghassem Gargari

Name of organization / entity

Health and Nutrition Faculty, Tabriz University of medical sciences

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Recruitment status

Recruitment complete

Funding source

Vice-chancellor for research, Tabriz University of Medical Science

Expected recruitment start date

2014-11-07, 1393/08/16

Expected recruitment end date

2015-03-20, 1393/12/29

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Effect of vitamin D supplementation on carotid intima-media thickness and risk factors of cardiovascular disease in patients with metabolic syndrome

Public title

vitamin D supplementation in metabolic syndrome

Purpose

Prevention

Inclusion/Exclusion criteria

Inclusion criteria: Willingness to participate; age 30-50 years; affected by metabolic syndrome with three out of five criteria: waist circumference >91 cm in women and >89 cm for men; serum triglyceride $\geq$ 150 mg/dL; fasting serum glucose $\geq$ 100 mg/dL; serum HDL-C < 40 mg/dL in men and < 50 mg/dL in women; systolic blood

pressure $\geq$ 130mmhg and/or diastolic blood pressure $\geq$ 85mmhg. Exclusion criteria: being menopause; taking vitamin D, calcium, fish oil or other antioxidant supplements for at least 3 months preceding the study; taking anti lipid or anti-hypertensive drugs; smoking; current clinical disease like diabetes mellitus; cardiovascular disease; cancers; liver or kidney disease; any symptoms of inflammation or having surgery; parathyroid abnormalities; using corticosteroids, calcitonin, bisphosphonates for at least 3 months preceding the study; spiro or crohn disease; current diet therapy; pregnancy or lactation.

Age

From **30 years** old to **50 years** old

Gender

Both

Phase

N/A

Groups that have been masked

No information

Sample size

Target sample size: **80**

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**

Ethics Committee of Tabriz University of Medical Sciences

Street address

Attar Neyshaboori Street, Golgasht street, Tabriz University of Medical Sciences

City

Tabriz

Postal code**Approval date**

2014-08-01, 1393/05/10

Ethics committee reference number

93100

Health conditions studied**1****Description of health condition studied**

metabolic syndrome

ICD-10 code

E88.9

ICD-10 code description

metabolic disorders not specified

Primary outcomes**1****Description**

serum 25-hydroxyvitamin vitamin D

Timepoint

befor and after intervention

Method of measurement

chemiluminescence immunoassay

2**Description**

carotid intima media thickness

Timepoint

baseline and 4 months after intervention

Method of measurement

ultrasonography

Secondary outcomes**1****Description**

serum inflammatory markers

Timepoint

baseline and 4 months after intervation

Method of measurement

ELISA

2**Description**

Glycemic factors

Timepoint

baseline and 4 months after intervation

Method of measurement

enzymatic

3**Description**

Lipid profiles

Timepoint

baseline and 4 months after intervation

Method of measurement

enzymatic colorimetric

4**Description**

Blood pressure

Timepoint

baseline, 2 and 4 months after intervention
Method of measurement
digital sphygmomanometer

5

Description
anthropometry markers
Timepoint
baseline , 2 and 4 months after intervention
Method of measurement
tape, scale, impedance analysis

Intervention groups

1

Description
Intervention: 50000 IU vitamin D3 every week for 4 months
Category
Prevention

2

Description
Control group: placebo
Category
Placebo

Recruitment centers

1

Recruitment center
Name of recruitment center
Faculty of Nutrition, Tabriz University of Medical Sciences
Full name of responsible person
Dr. Pourgasem Gargari
Street address
Golgashat Ave, Attar Neyshaboori St, Faculty of Nutrition, Tabriz University of Medical Sciences
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Sponsors / Funding sources

1

Sponsor
Name of organization / entity
Vice chancellor for research, Tabriz University of Medical Sciences
Full name of responsible person
Dr. Mohammad Reza Rashidi
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Attar Neyshaboori St, Golgasht Ave, Tabriz University of Medical Sciences
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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
Vice chancellor for research, Tabriz 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