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, after2 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

Country

Iran (Islamic Republic of)

Phone

+98 41 1435 7580

Email address

pourghassemb@tbzmed.ac.ir

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≥150 mg/dL; fasting serum glucose≥100mg/dL; serum HDL-C<40 mg/dL in men and <50 mg/dl in women; systolic blood

pressure≥130mmhg and/or diastolic blood pressure≥ 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 intervation

Method of measurement

digital sphygmomanometer

5

Description

anthropometry markers

Timepoint

baseline , 2 and 4 months after intervation

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 Sceinces

Full name of responsible person

Dr. Pourgasem Gargari

Street address

Golgasht Ave, Attar Neyshaboori St, Faculty of Nutrition, Tabriz University of Medical Sciences

City

Tabriz

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

Street address

Attar Neyshaboori St, Golgasht Ave, Tabriz University of Medical Sciences

City

Tabriz

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

Contact

Name of organization / entity

Faculty of Nutrition, Tabriz University pf Medical Sciences

Full name of responsible person

Shabnam Salekzamani

Position

Ph.D candidate of Nutrition

Other areas of specialty/work

Street address

Attar Neyshaboori St, Golgasht Ave, Faculty of Nutrition, Tabriz University of Medical Sciences

City

Tabriz

Postal code

Phone

+98 41 3335 7580

Fax

Email

salekzamanish@gmail.com

Web page address

Person responsible for scientific inquiries

Contact

Name of organization / entity

Faculty of Nutrition, Tabriz University of Medical Sciences

Full name of responsible person

Dr. Bahram Pourghasem Gargari

Position

Ph.D of Nutrition

Other areas of specialty/work

Street address

Attar Neyshaboori St, Golgasht Ave, Faculty of Nutrition, Tabriz University of Medical Sciences

City

Tabriz

Postal code

Phone

+98 41 3335 7580

Fax

Email

bahrampg@yahoo.com

Web page address

Person responsible for updating data

Contact

Name of organization / entity

Faculty of Nutrition, Tabriz University of Medical Sciences

Full name of responsible person

Shabnam Salekzamani

Position

Ph.D candidate of Nutrition

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Street address

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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