

Clinical Trial Protocol

Iranian Registry of Clinical Trials

30 Jun 2026

Comparison of combination therapy with vitamin D, calcium and statin with statin alone in reducing blood cholesterol in patients with hypercholesterolemia

Protocol summary

Study aim

This study aims to evaluate the effectiveness of supplemental vitamin D3 and calcium in addition to standard treatment (Statin therapy) for treatment of hypercholesterolemia.

Design

In this study, 80 new-case of hypercholesterolemia, who referred to internal medicine clinic in Army hospital were recruited. This study was a crossover study and we had no control group. All interventions were performed on a single group of patients.

Settings and conduct

At first all patients were treated with Atorvastatin, 20 mg, daily and lipid profile was checked after 6 weeks. In second phase, participant received vitamin D3, 400 IU, daily and Calcium, 1 gr, daily in addition to 20 mg Atorvastatin for 6 weeks. Thereafter, lipid profile was rechecked for all patients. Finally, before and after lipid profile measures were compared. We had no blinding in this study.

Participants/Inclusion and exclusion criteria

Patients who had WHO criteria for hypercholesterolemia were included in this study. Patients who had been administered lipid-lowering agents in last one month and supplemental vitamin D3 and calcium in last six months were excluded from study.

Intervention groups

400 IU oral vitamin D3 daily and 1 gr oral Calcium daily for 6 weeks

Main outcome variables

1. Triglyceride 2. Total cholesterol 3. LDL 4. HDL

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20171007036613N1**

Registration date: **2018-01-03, 1396/10/13**

Registration timing: **retrospective**

Last update: **2018-01-03, 1396/10/13**

Update count: **0**

Registration date

2018-01-03, 1396/10/13

Registrant information

Name

Ali Sanjari Moghaddam

Name of organization / entity

Shahid Beheshti university of medical sciences

Country

Iran (Islamic Republic of)

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Recruitment status

Recruitment complete

Funding source

Vice chancellor for research, Aja University of Medical Science

Expected recruitment start date

2016-12-10, 1395/09/20

Expected recruitment end date

2017-06-10, 1396/03/20

Actual recruitment start date

2016-11-10, 1395/08/20

Actual recruitment end date

2017-06-10, 1396/03/20

Trial completion date

empty

Scientific title

Comparison of combination therapy with vitamin D, calcium and statin with statin alone in reducing blood cholesterol in patients with hypercholesterolemia

Public title

Effect of vitamin D3 and calcium on blood lipid

Purpose

Treatment

Inclusion/Exclusion criteria

Inclusion criteria:

LDL above 160 mg/dl without or with one of cardiovascular risk factors. LDL above 130 mg/dl with two or more cardiovascular risk factors. LDL above 100 mg/dl in diabetics and patients with history of CVD. Total cholesterol above 240.

Exclusion criteria:

Triglyceride above 400 mg/dl. Taking Lipid-lowering agent within one month before recruitment. Supplementary calcium and vitamin D in last 6 months.

Age

No age limit

Gender

Both

Phase

N/A

Groups that have been masked

No information

Sample size

Target sample size: **80**

Actual sample size reached: **65**

Randomization (investigator's opinion)

N/A

Randomization description

Blinding (investigator's opinion)

Not 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 Aja University of Medical Sciences

Street address

Aja University of Medical Sciences, Etemadzadeh avenue., Fatemi street., Tehran, Iran

City

Tehran

Province

Tehran

Postal code

1411718541

Approval date

2016-11-26, 1395/09/06

Ethics committee reference number

IR.AJAUMS.REC.1395.23

Health conditions studied

1

Description of health condition studied

hypercholesterolemia

ICD-10 code

E78.0

ICD-10 code description

Pure hypercholesterolaemia

Primary outcomes

1

Description

Triglyceride

Timepoint

Before intervention, 6 weeks after first intervention and 6 weeks after second intervention

Method of measurement

Lab test

2

Description

HDL

Timepoint

Before intervention, 6 weeks after first intervention and 6 weeks after second intervention

Method of measurement

Lab test

3

Description

Total cholesterol

Timepoint

Before intervention, 6 weeks after first intervention and 6 weeks after second intervention

Method of measurement

Lab test

4

Description

LDL

Timepoint

Before intervention, 6 weeks after first intervention and 6 weeks after second intervention

Method of measurement

Lab test

Secondary outcomes

1

Description

Blood pressure

Timepoint

Before intervention, 6 weeks after first intervention and 6 weeks after second intervention

Method of measurement

Sphygmomanometer

2

Description

Body mass index

Timepoint

Before intervention, 6 weeks after first intervention and 6 weeks after second intervention

Method of measurement

Standing scale for weight and tape for height

Intervention groups

1

Description

At first, all patients were treated by Atorvastatin 20 mg once daily for six weeks. The second intervention in all patients was adding vitamin D3, 400 IU/day and calcium, 1gr/day (CalTrex capsule once per 12 hour) to prior regimen for six weeks.

Category

Treatment - Drugs

Recruitment centers

1

Recruitment center

Name of recruitment center

Internal medicine clinic, 501 Army hospital

Full name of responsible person

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Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Vice chancellor for research, Aja University of Medical Sciences

Full name of responsible person

Dr. Armin Zareian

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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, Aja University of Medical Sciences

Proportion provided by this source

100

Public or private sector

Public

Domestic or foreign origin

Domestic

Category of foreign source of funding

empty

Country of origin

Type of organization providing the funding

Academic

Person responsible for general inquiries

Contact

Name of organization / entity

Aja University of Medical Sciences

Full name of responsible person

Ali Sanjari Moghaddam

Position

MD

Latest degree

Medical doctor

Other areas of specialty/work

General Practitioner

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Sharing plan

Deidentified Individual Participant Data Set (IPD)

Yes - There is a plan to make this available

Study Protocol

Yes - There is a plan to make this available

Statistical Analysis Plan

Yes - There is a plan to make this available

Informed Consent Form

Yes - There is a plan to make this available

Clinical Study Report

Yes - There is a plan to make this available

Analytic Code

Undecided - It is not yet known if there will be a plan to make this available

Data Dictionary

Undecided - It is not yet known if there will be a plan to make this available

Title and more details about the data/document

individual participant data collected for the primary and secondary outcome measure

When the data will become available and for how long

After publication for one year

To whom data/document is available

for all people who request for data

Under which criteria data/document could be used

all types of analysis all allowed. But, use of data for publication is not allowed.

From where data/document is obtainable

corresponding author of article

What processes are involved for a request to access data/document

after request to corresponding author, data will send within one week.

Comments