

Clinical Trial Protocol

Iranian Registry of Clinical Trials

07 Jun 2026

The effect of vitamin D deficiency treatment on lipid profile in ischemic heart diseases: a double blinded randomized clinical trial

Protocol summary

Study aim

The effect of vitamin D deficiency treatment on lipid profile in ischemic heart diseases Determination and comparison of mean triglyceride, total cholesterol, HDL, LDL serum levels before and two months after treatment in both groups

Design

Randomized clinical trial, Double blind, Parallel groups, Randomised using Randomized block design, 66 samples divided in 2 groups

Settings and conduct

Patients suspected to acute coronary syndrome who are transferred to the emergency room of Isfahan Chamran Hospital, including ischemic heart disease criteria and vitamin D deficiency are entered the study and a personal consent is given. Lipid profile tests will be done initially and patients are divided into two groups: recipients of pearls containing the drug and placebo. Patients receive one pill each week for two months. Then, the mentioned parameters are measured again and their information is recorded. Study is double blinded including both patients and investigators.

Participants/Inclusion and exclusion criteria

Inclusion criteria: Vitamin D deficiency (<30 ng/ml) Age: 40 to 65 years Ischemic heart disease : including acute coronary syndrome , stable angina Excluding criteria: Having coronary artery bypass criteria Any life-threatening underlying disease Getting any vitamin supplements

Intervention groups

vitamin D deficiency is treated by receiving 50,000 units of vitamin D pearls per week, for up to 2 months and receiving a placebo by the control group similar to the treated group. The control group is given medication for vitamin D deficiency after the study.

Main outcome variables

Triglyceride, Total cholesterol, HDL, LDL serum levels after getting vitamin D supplement

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20200905048622N1**

Registration date: **2020-09-17, 1399/06/27**

Registration timing: **prospective**

Last update: **2020-09-17, 1399/06/27**

Update count: **0**

Registration date

2020-09-17, 1399/06/27

Registrant information

Name

Ali Momeni

Name of organization / entity

Country

Iran (Islamic Republic of)

Phone

+98 31 3264 8083

Email address

amomeni10@gmail.com

Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2020-10-11, 1399/07/20

Expected recruitment end date

2020-12-15, 1399/09/25

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

The effect of vitamin D deficiency treatment on lipid profile in ischemic heart diseases: a double blinded randomized clinical trial

Public title

The effect of vitamin D deficiency treatment on lipid profile in ischemic heart diseases

Purpose

Supportive

Inclusion/Exclusion criteria**Inclusion criteria:**

Vitamin D level less than 30 ng/ml Ischemic heart disease : stable angina , acute coronary syndrome Age from 40 to 65 years

Exclusion criteria:

Coronary artery bypass grafting (CABG) indications Any life threatening disease Any vitamin supplementation use Severe vitamin D deficiency (< 10 ng / ml)

Age

From **40 years** old to **65 years** old

Gender

Both

Phase

3

Groups that have been masked

- Participant
- Care provider
- Investigator

Sample size

Target sample size: **66**

Randomization (investigator's opinion)

Randomized

Randomization description

The patients were allocated into intervention or control group using block randomization method to keep an even randomization ratio of (1:1). If the patient had inclusion criteria and did not excluded from the study according to above mentioned protocol, the random number generating software was used to determine their designated group. Numbers were between 0-9. If the number was even, the letter "A" was wrote at the top of their checklist by the examining physician, and if the number was odd, the letter "B" was used. Then, the next patient had to be assigned to the opposite group. This process repeated for the upcoming patients and continued until we reached our estimated sample size. After completing the study and before starting the data analysis process, the encrypted letters will be revealed by the pharmaceutical company.

Blinding (investigator's opinion)

Double blinded

Blinding description

Double blinded including both participants and investigators.

Placebo

Used

Assignment

Parallel

Other design features**Secondary Ids**

empty

Ethics committees**1****Ethics committee****Name of ethics committee**

Ethics committee of isfahan university of medical sciences

Street address

Ethics committee of isfahan university of medical sciences, Faculty of medicine, Hezarjarib St.

City

Isfahan

Province

Isfahan

Postal code

8174673461

Approval date

2020-05-10, 1399/02/21

Ethics committee reference number

IR.MUI.MED.REC.1399.135

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

Ischemic heart disease, Vitamin D deficiency

ICD-10 code**ICD-10 code description****Primary outcomes****1****Description**

Low Density Lipoprotein (LDL), High Density Lipoprotein (HDL), triglyceride, total cholesterol

Timepoint

before intervention and after 2 months (end of the study)

Method of measurement

laboratory kit

Secondary outcomes

empty

Intervention groups**1****Description**

Intervention group: getting oral vitamin D 50000 IU pearl weekly up to 2 months, zahravi pharmaceutical company

Category

Treatment - Drugs

2

Description

Control group: getting oral Vitamin D placebo pearl with the same shape as the main drug made by Zahravi Pharmaceutical Company, once a week up to 2 months.

Category

Placebo

Recruitment centers

1

Recruitment center

Name of recruitment center

Shahid Chamran heart hospital

Full name of responsible person

Masoumeh Sadeghi

Street address

Chamran Heart rehabilitation Research center,
Moshtagh 3 Blvd

City

Isfahan

Province

Isfahan

Postal code

8158388994

Phone

+98 31 3611 5204

Email

sadeghimasoumeh@gmail.com

Web page address

Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Esfahan University of Medical Sciences

Full name of responsible person

Masoumeh Sadeghi

Street address

Research assistance, Faculty of medicine, Hezarjarib
St.

City

Isfahan

Province

Isfahan

Postal code

8158388994

Phone

+98 31 3611 5204

Email

sadeghimasoumeh@gmail.com

Grant name

Grant code / Reference number

Is the source of funding the same sponsor organization/entity?

Yes

Title of funding source

Esfahan 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

Esfahan University of Medical Sciences

Full name of responsible person

Masoumeh Sadeghi

Position

Professor

Latest degree

Specialist

Other areas of specialty/work

Cardiology

Street address

Chamran heart hospital , Moshtagh 3 St.

City

Isfahan

Province

Isfahan

Postal code

8158388994

Phone

+98 31 3611 5204

Email

sadeghimasoumeh@gmail.com

Person responsible for scientific inquiries

Contact

Name of organization / entity

Esfahan University of Medical Sciences

Full name of responsible person

Masoumeh Sadeghi

Position

Professor

Latest degree

Specialist

Other areas of specialty/work

Cardiology

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City

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Province

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Postal code

8158388994

Phone

+98 31 3611 5204

Email

sadeghimasoumeh@gmail.cim

Person responsible for updating data**Contact****Name of organization / entity**

Esfahan University of Medical Sciences

Full name of responsible person

Ali Momeni

Position

Intern

Latest degree

A Level or less

Other areas of specialty/work

General Practitioner

Street address

Chamran Heart Hospital, Moshtagh 3 St.

City

Isfahan

Province

Isfahan

Postal code

8158388994

Phone

+98 31 3611 5204

Email

amomeni10@gmail.com

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

Yes - There is a plan to make this available

Data Dictionary

Yes - There is a plan to make this available

Title and more details about the data/document

IPD collected for the primary outcome measure only

When the data will become available and for how long

starting 6 months after publication

To whom data/document is available

for people working in academic institutions

Under which criteria data/document could be used

any analysis

From where data/document is obtainable

email addresses

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

After receiving the e-mail and determining the required data and analyzes on which the data is to be performed and with the consent of the project manager and research assistant The information is provided to the applicant.

Comments