Clinical Trial Protocol
Iranian Registry of Clinical Trials

18 Sep 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
Isfehan
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
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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.
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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
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
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Person responsible for scientific inquiries

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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

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Chamran Heart Hospital, Moshtagh 3 St.

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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
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