

Clinical Trial Protocol

Iranian Registry of Clinical Trials

05 Jul 2026

Clinical trials to investigate the effect of vitamin D supplementation on serum levels of heat shock protein 60 in patients with coronary heart disease

Protocol summary

Summary

One of the most common cardiovascular disease is atherosclerosis that begins with inflammation of the artery walls and cause endothelial dysfunction, plaque vulnerability and rupture, and atherosclerotic plaque rupture that leading to partial or complete blockage of the coronary arteries is the most common cause of Coronary Heart Disease. Recent studies have shown that atherosclerotic lesions topically in the form of a family of proteins called heat shock proteins and specifically the family of heat shock 60-accumulate, causing penetrate T cells to the vascular wall and thus stimulate the secretion of inflammatory factors. On the other hand relation between Vitamin D deficiency and risk of cardiovascular disease with increased inflammatory markers have shown. So the present study is a double blind clinical trial to investigate the effect of vitamin D supplementation on serum levels of heat shock protein 60 in patients with coronary heart disease was developed. 80 people, ages 30 to 60 years, in accordance with the conditions of the study will be recruited from Rasool Akram Hospital. Informed consent form will be completed by each participant at the beginning of study. The participants were randomly divided into two groups: receiving either 50000 IU vitamin D or placebo for 8 week. At the beginning and end of the study, heat shock protein 60, vitamin D, inflammatory markers, Pro oxidant antioxidant balance, lipid profile will measure.

General information

Acronym

IRCT registration information

IRCT registration number: **IRCT201612122365N14**

Registration date: **2017-01-10, 1395/10/21**

Registration timing: **registered_while_recruiting**

Last update:

Update count: **0**

Registration date

2017-01-10, 1395/10/21

Registrant information

Name

Mohammad Reza Vafa

Name of organization / entity

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Recruitment status

Recruitment complete

Funding source

School of Public Health, Iran University of Medical Sciences

Expected recruitment start date

2016-09-22, 1395/07/01

Expected recruitment end date

2017-03-20, 1395/12/30

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Clinical trials to investigate the effect of vitamin D supplementation on serum levels of heat shock protein 60 in patients with coronary heart disease

Public title

The effect of vitamin D supplement on treatment and prevention of Coronary Heart Disease

Purpose

Treatment

Inclusion/Exclusion criteria

Inclusion criteria: Age 30 to 60 years; women and men with coronary heart disease ; Willingness to participate in research exclusion criteria: BMI >35 kg / m²; Vitamin D levels higher than 30 ng / ml; Disease (cancer, myocardial infarction, diabetes, liver problems and kidney); Drugs using out of treatment protocol; Using oral and injectable nutritional supplements for at least the last 4 months (vitamins D, C, E, calcium, magnesium, potassium and multivitamins, omega-3); Using any herbal remedies; Consumption any foods fortified with vitamin D; pregnancy and lactation; Smoking; Alcohol consumption withdraw criteria: Consume less than 7 tablets of 8 tablet at the end of the study ; The occurrence of any event that may affect the health; Any acute illness during the study; Unwillingness to continue cooperation in research

Age

From **30 years** old to **60 years** old

Gender

Both

Phase

3

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

Iran University of Medical Science

Street address

Iran University of Medical Science, Hemat highway,
Tehran, Iran

City

Tehran

Postal code

1449614535

Approval date

2016-08-10, 1395/05/20

Ethics committee reference number

IR.IUMS.REC 1395.95-02-27-9411323003

Health conditions studied

1

Description of health condition studied

Coronary Heart Disease

ICD-10 code

I25.0

ICD-10 code description

Atherosclerotic cardiovascular disease, so described

Primary outcomes

1

Description

Heat Shock Protein 60

Timepoint

before and 2 month after intervention

Method of measurement

ng/ml by ELISA

Secondary outcomes

1

Description

Physical Activity

Timepoint

Before and two months after intervention

Method of measurement

According to MET-minutes / week by 7 days questionnaire of physical activity

2

Description

Level of physical activity

Timepoint

Before and two months after intervention

Method of measurement

According to three conditions: light, medium and intense physical activity by 7 days questionnaire

3

Description

sun exposure

Timepoint

Before and two months after intervention

Method of measurement

According to time (minutes) per day using 24 hour recall questionnaire

4

Description

Dietary calcium intake

Timepoint

Before and two months after intervention

Method of measurement

mg/day by 24 hour recall questionnaire

5**Description**

dietary vitamin d intake

Timepoint

Before and two months after intervention

Method of measurement

unit/day by 24 hour recall questionnaire

6**Description**

prothrombin hormone (PTH)

Timepoint

Before and two months after intervention

Method of measurement

pg/ml by ELISA

7**Description**

energy intake

Timepoint

Before and two months after intervention

Method of measurement

kcal/day by 24 hour recall questionnaire

8**Description**

Muscle mass and body fat percentage

Timepoint

Before and two months after intervention

Method of measurement

percentage by Beurer devices

9**Description**

waist circumference

Timepoint

Before and two months after intervention

Method of measurement

cm by metre

10**Description**

25(OH)D3

Timepoint

Before and two months after intervention

Method of measurement

nmol/l by ELISA

11**Description**

Body mass index

Timepoint

Before and two months after intervention

Method of measurement

kg/m² by Calculate the ratio of the weight by the square of height

12**Description**

blood pressure

Timepoint

Before and two months after intervention

Method of measurement

mmHg by Mercury manometers

13**Description**

Triglyceride

Timepoint

Before and two months after intervention

Method of measurement

mg/dl by Biochemical auto analyzer

14**Description**

Total cholesterol

Timepoint

Before and two months after intervention

Method of measurement

mg/dl by Biochemical auto analyzer

15**Description**

High Density Lipoprotein (HDL)

Timepoint

Before and two months after intervention

Method of measurement

mg/dl by Biochemical auto analyzer

16**Description**

Pro-oxidant- antioxidant balance

Timepoint

Before and two months after intervention

Method of measurement

HK-unit by Photometric method

17**Description**

Low Density Lipoprotein (LDL)

Timepoint

Before and two months after intervention

Method of measurement

mg/dl by Biochemical auto analyzer

18**Description**

Tumor Necrosis Factor- α (TNF- α)

Timepoint

Before and two months after intervention
Method of measurement
pg/ml by ELISA

19

Description
Interleukin-17 (IL-17)
Timepoint
Before and two months after intervention
Method of measurement
pg/ml by ELISA

20

Description
weight
Timepoint
Before and two months after intervention
Method of measurement
kg by Digital scale

Intervention groups

1

Description
vitamin d supplement, 50000 IU, 1 time per week for 8 weeks
Category
Treatment - Drugs

2

Description
placebo, 50000 IU, 1 time per week for 8 weeks
Category
Treatment - Drugs

Recruitment centers

1

Recruitment center
Name of recruitment center
Rasool-e-Akram hospital
Full name of responsible person
seyed hashem sezavar
Street address
Hazrat-e Rasool General Hospital, Niyayesh St.,
Satarkhan St., Tehran, Iran
City
Tehran

Sponsors / Funding sources

1

Sponsor
Name of organization / entity
Iran University of Medical Science
Full name of responsible person

mohammadreza vafa

Street address
Iran University of Medical Science, beside milad
hospital, shahid hemat high way, Tehran, Iran
City
Tehran

Grant name
Grant code / Reference number
Is the source of funding the same sponsor organization/entity?
Yes
Title of funding source
Iran University of Medical Science
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
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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