

# 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

Iran University of Medical Sciences

###### Country

Iran (Islamic Republic of)

###### Phone

+98 21 8670 4734

###### Email address

vafa.m@iums.ac.ir

##### 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 / m<sup>2</sup>; 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/m<sup>2</sup> 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- $\alpha$  (TNF- $\alpha$ )

**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**

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**Full name of responsible person**  
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## **Person responsible for scientific inquiries**

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medical science, beside milad tower, shahid hemat

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**City**

Tehran

**Postal code**

**Phone**

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**Email**

**Web page address**

**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*