

# Clinical Trial Protocol

## Iranian Registry of Clinical Trials

11 Sep 2026

### The effect of preoperative 1, 25 (OH)<sub>2</sub> vitamin D administration on postoperative serum levels of Interleukin 1, Interleukin 6 and Tumor Necrosis Factor-alpha in patients undergoing elective CABG

#### Protocol summary

##### Summary

the aim of study: to determine the effect of 1,25 Vit D<sub>3</sub> administered before operation in elective Coronary Artery Bypass Graft on postoperative serum inflammatory factors Study design: randomized, double blind, placebo controlled, single centered, stage 3 of clinical trial Study population: patients candidates for elective Coronary Artery Bypass Graft in entering Shahid Modarres cardiac surgery OR. Inclusion criteria: 1- age 40-75 2- elective Coronary Artery Bypass Graft surgery with CPB 3- constant surgeon Exclusion criteria 1- Diabetes mellitus 2- Chronic Renal failure (Cr>2mg/dL) before anesthesia 3- chronic renal failure (impaired Liver Function Test) 4- elevated or decreased level of Vit D<sub>3</sub> (out of normal range) 5- off pump Coronary Artery Bypass Graft 6- any complications during surgery 7- Pulmonary artery pressure>35 mmHg 8- Ejection Fraction of left ventricle (preoperative) <30% 9- repeated operation during early postoperative period Sample size: totally 80 patients (40 in each group) Intervention: Vit D administration and assessment of its effects on inflammatory response of the body Time of intervention: 2015 (=1394) Primary outcome for measurement: the systemic inflammatory response of the body which is assessed based on the serum levels of inflammatory interleukins

#### General information

##### Acronym

##### IRCT registration information

IRCT registration number: **IRCT201502022804N7**  
Registration date: **2015-05-17, 1394/02/27**  
Registration timing: **registered\_while\_recruiting**

Last update:

Update count: **0**

##### Registration date

2015-05-17, 1394/02/27

##### Registrant information

###### Name

Ali Dabbagh

###### Name of organization / entity

###### Country

Iran (Islamic Republic of)

###### Phone

+98 21 2243 2572

###### Email address

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##### Recruitment status

###### Recruitment complete

##### Funding source

Research Deputy, Shahid Beheshti University of Medical Sciences, Tehran, Iran

##### Expected recruitment start date

2015-03-21, 1394/01/01

##### Expected recruitment end date

2017-03-21, 1396/01/01

##### Actual recruitment start date

empty

##### Actual recruitment end date

empty

##### Trial completion date

empty

##### Scientific title

The effect of preoperative 1, 25 (OH)<sub>2</sub> vitamin D administration on postoperative serum levels of Interleukin 1, Interleukin 6 and Tumor Necrosis Factor-alpha in patients undergoing elective CABG

##### Public title

The effect of preoperative vitamin D administration on postoperative serum levels of Interleukin 1, Interleukin 6

and Tumor Necrosis Factor-alpha in patients undergoing elective CABG

#### **Purpose**

Prevention

#### **Inclusion/Exclusion criteria**

Inclusion criteria: Age 40-75; elective Coronary Artery Bypass Graft with CardioPulmonary Bypass; constant surgeon Exclusion criteria: informed written consent; diabetes mellitus; chronic kidney disease causing serum Cr>2mg/dL; hepatic failure causing liver function test failure; high levels of vitamin D; off pump Coronary Artery Bypass Graft; any unwanted complication in the operation period; re-starting CPB after weaning from bypass; Pulmonary artery pressure >30 before operation; Ejection Fraction<30%; re-operation in the postoperative period

#### **Age**

From **40 years** old to **75 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**

Ethics Committee, Shahid Beheshti University of Medical Sciences

###### **Street address**

Velenjak

###### **City**

Tehran

###### **Postal code**

1417613151

##### **Approval date**

2014-09-23, 1393/07/01

##### **Ethics committee reference number**

4

### **Health conditions studied**

#### **1**

##### **Description of health condition studied**

coronary artery bypass graft

##### **ICD-10 code**

I25.1

##### **ICD-10 code description**

Atherosclerotic heart disease

### **Primary outcomes**

#### **1**

##### **Description**

serum cytokines after CABG

##### **Timepoint**

serum cytokines are measure preoperatively as baseline and the after operation

##### **Method of measurement**

serum levels detected by ELISA

### **Secondary outcomes**

#### **1**

##### **Description**

duration of surgery

##### **Timepoint**

duration of anesthesia

##### **Method of measurement**

cardiopulmonary bypass time

### **Intervention groups**

#### **1**

##### **Description**

In the intervention group, the patients receive 3 vitamin D pearls each day (each pearl is 50000 units; so 150000 units of vitamin D in each day); these pearls start 1 week before surgery The pearls are made by Dana Pharmaceuticals, Tabriz, Iran

##### **Category**

Treatment - Drugs

#### **2**

##### **Description**

The control group receives placebo, 3 times a day before one week starting before operation

##### **Category**

Placebo

### **Recruitment centers**

#### **1**

##### **Recruitment center**

**Name of recruitment center**

Shahid Modarres Hospital  
**Full name of responsible person**  
Ali Dabbagh  
**Street address**  
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## Person responsible for scientific inquiries

### Contact

**Name of organization / entity**  
Anesthesiology Research Center  
**Full name of responsible person**  
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## Person responsible for updating data

### Contact

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## Sharing plan

**Deidentified Individual Participant Data Set (IPD)**  
*empty*  
**Study Protocol**  
*empty*  
**Statistical Analysis Plan**

## Sponsors / Funding sources

### 1

#### Sponsor

**Name of organization / entity**  
Vice chancellor for research, Shahid Beheshti  
University of Medical Sciences  
**Full name of responsible person**  
Dr Afshin Zarghi  
**Street address**  
Shahid Beheshti University of Medical Sciences,  
Velenjak, Chamran Exp Way  
**City**  
Tehran  
**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, Shahid Beheshti University  
of Medical Sciences  
**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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*empty*  
**Informed Consent Form**  
*empty*  
**Clinical Study Report**  
*empty*

**Analytic Code**  
*empty*  
**Data Dictionary**  
*empty*