

Clinical Trial Protocol

Iranian Registry of Clinical Trials

10 Jun 2026

The effect of preoperative 1, 25 (OH)₂ 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 D₃ 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 D₃ (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

alidabbagh@sbmu.ac.ir

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)₂ 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
Cardiac Anesthesiology Dept. Shahid Modarres
Hospital, Saadat Abad, Tehran, Iran
City
Tehran

0000982122432572; 00982122074090
Fax
Email
alidabbagh@yahoo.com; alidabbagh@sbbmu.ac.ir
Web page address

Person responsible for scientific inquiries

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

Name of organization / entity
Anesthesiology Research Center
Full name of responsible person
Ali Dabbagh
Position
MD, Professor
Other areas of specialty/work
Street address
Anesthesiology Research Center, Taleghani Hospital,
Velenjak
City
Tehran
Postal code
1417613151
Phone

Contact

Name of organization / entity
Anesthesiology Research Center
Full name of responsible person
Ali Dabbagh
Position
MD, Professor of Cardiac Anesthesiology
Other areas of specialty/work
Street address
Anesthesiology Research Center, 4th Floor, Ayatollah
Taleghani Hospital, Velenjak, Chamran Exp Way,
Tehran, Iran
City
Tehran
Postal code
1417613151
Phone
00982122432572; 00982122074090
Fax
Email
alidabbagh@yahoo.com; alidabbagh@sbbmu.ac.ir
Web page address

Person responsible for updating data

Contact

Name of organization / entity
Anesthesiology Research Center
Full name of responsible person
Ali Dabbagh
Position
MD, Professor of Cardiac Anesthesiology
Other areas of specialty/work
Street address
Anesthesiology Research Center
City
Tehran
Postal code
1417613151
Phone
+98 21 2243 2572
Fax
Email
alidabbagh@yahoo.com
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