Clinical Trial Protocol
Iranian Registry of Clinical Trials

07 Nov 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

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Ali Dabbagh
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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)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

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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
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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

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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
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

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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