

# Clinical Trial Protocol

## Iranian Registry of Clinical Trials

28 May 2026

### association between vitamin D administration and pathological feature of cardiac cell in patients with low Vitamin D who are candidates for coronary artery bypass graft(CABG) surgery for the first time

#### Protocol summary

##### Study aim

Determine the effect of Vitamin D supplement administration on pathological feature of cardiomyopathy in patients whom had Vitamin D insufficiency and refer to hospital for coronary artery bypass graft (CABG)

##### Design

Two arm parallel group randomised trial with blinded postoperative care and outcome assessment

##### Settings and conduct

This study was conducted in cardiac surgery ward in Shaheed Modarres Hospital. Patients were assigned by a computerized software into two groups. After the intervention, we will measure Apoptosis indicators including: Caspase 2, Caspase 3, Caspase 7, Insulin GF, IL-10 in three sets of times: 3 days before surgery and the day of surgery and one day after surgery. Caspase enzyme will be measured by immunohistochemistry (IHC) and other factors will be measured by ELISA. IHC will be done on right atrium auricle. In this study patients, laboratory technicians, pathologist and statistician were blind.

##### Participants/Inclusion and exclusion criteria

Inclusion criteria :1. Patients whom having CABG for the first time 2. Patients only with coronary surgery and no valvular one 3. Patients that have surgery with cardiopulmonary pump 4. Patients with Vitamin D level less than 30 ng/ml Exclusion criteria : 1. Patients with Renal failure or creatinine level more than 1.5 mg/dl 2. Patients who have been Vitamin D taken

##### Intervention groups

controlled group: 33 patients that will receive placebo for 3 days and each day for 3 doses intervention group is 33 patients that pass the inclusion criteria and do not have exclusion criteria that will receive Vitamin D for 3 days and each time 3 doses of 50000 units

##### Main outcome variables

Caspase 2, 3, 7 serum level of IL-10, Insulin growth

factor

#### General information

##### Reason for update

##### Acronym

##### IRCT registration information

IRCT registration number: **IRCT20180118038423N1**

Registration date: **2018-12-25, 1397/10/04**

Registration timing: **retrospective**

Last update: **2018-12-25, 1397/10/04**

Update count: **0**

##### Registration date

2018-12-25, 1397/10/04

##### Registrant information

##### Name

Erfan Tasdighi

##### Name of organization / entity

##### Country

Iran (Islamic Republic of)

##### Phone

+98 21 2207 4087

##### Email address

drerfan.tasdighi@sbmu.ac.ir

##### Recruitment status

**Recruitment complete**

##### Funding source

##### Expected recruitment start date

2018-10-20, 1397/07/28

##### Expected recruitment end date

2018-12-23, 1397/10/02

##### Actual recruitment start date

empty

##### Actual recruitment end date

empty

**Trial completion date**

empty

**Scientific title**

association between vitamin D administration and pathological feature of cardiac cell in patients with low Vitamin D who are candidates for coronary artery bypass graft(CABG) surgery for the first time

**Public title**

Can Vitamin D reduce heart damage in cardiac surgery

**Purpose**

Prevention

**Inclusion/Exclusion criteria****Inclusion criteria:**

patients that have CABG surgery for the first time patients only with coronary surgery and no valvular surgery patients that we use cardipulmonary pump during the surgery patients with vitamin D level less than 30 ng/ml

**Exclusion criteria:**

Patients who have Renal failure creatinine higher than 1.5 mg/dl

**Age**

No age limit

**Gender**

Both

**Phase**

3

**Groups that have been masked**

- Participant
- Investigator
- Data analyser

**Sample size**

Target sample size: 66

**Randomization (investigator's opinion)**

Randomized

**Randomization description**

Method of randomization was simple and its unit was individuals. we used a computer software for randomization. For allocation concealment all of the ICU nurses that took care of patients, lab technicians who did the ELISA, pathologist who did the IHC and all the patients were not aware of the randomization process.

**Blinding (investigator's opinion)**

Double blinded

**Blinding description**

Each patient will assign to a specific code and they will receive a same looking drug

**Placebo**

Used

**Assignment**

Parallel

**Other design features****Secondary Ids****1****Registry name**

ISRCTN registry

**Secondary trial Id**

35981

**Registration date**

2018-11-17, 1397/08/26

**Ethics committees****1****Ethics committee****Name of ethics committee**

ethics committee of Shahid Beheshti medical university

**Street address**

7th Floor, Bldg No.2 SBUMS, Arabi Ave, Daneshjoo Blvd, Velenjak, Tehran, Iran.

**City**

Tehran

**Province**

Tehran

**Postal code**

19839-63113

**Approval date**

2018-11-04, 1397/08/13

**Ethics committee reference number**

IR.SBMU.RETECH.REC.1397.616

**Health conditions studied****1****Description of health condition studied**

Vitamin d deficiency

**ICD-10 code**

E55

**ICD-10 code description**

Vitamin D deficiency

**2****Description of health condition studied**

Ischemic hypertrophy heart disease

**ICD-10 code**

I25.5

**ICD-10 code description**

Ischemic cardiomyopathy

**Primary outcomes****1****Description**

Caspase 2 enzyme level

**Timepoint**

Right after intervention(3 days before surgery)-The day of surgery -Next day after surgery

**Method of measurement**

Immunohistochemistry

**2****Description**

caspase 3 enzyme level

**Timepoint**

Right after intervention(3 days before surgery)-The day of surgery -Next day after surgery

**Method of measurement**

Immunohistochemistry

**3**

**Description**

Caspase 7 enzyme level

**Timepoint**

Right after intervention(3 days before surgery)-The day of surgery -Next day after surgery

**Method of measurement**

Immunohistochemistry

**4**

**Description**

IL-10 serum level

**Timepoint**

Right after intervention(3 days before surgery)-The day of surgery -Next day after surgery

**Method of measurement**

Blood test

**5**

**Description**

Insulin growth factor

**Timepoint**

Right after intervention(3 days before surgery)-The day of surgery -Next day after surgery

**Method of measurement**

blood test

**Secondary outcomes**

**1**

**Description**

Hemorrhage after surgery

**Timepoint**

Right after surgery

**Method of measurement**

Suction

**2**

**Description**

Blood units usage

**Timepoint**

During the surgery and after that

**Method of measurement**

Number of blood units

**3**

**Description**

How long we used the ventilator

**Timepoint**

Since the surgery

**Method of measurement**

ventilator

**4**

**Description**

kidney damage

**Timepoint**

After surgery

**Method of measurement**

blood test

**Intervention groups**

**1**

**Description**

Control group: 33 patients that receive placebo for 3 days before the surgery and each day 3 doses

**Category**

Placebo

**2**

**Description**

Intervention group: A 33 patients that receive Vitamin D for 3 days before and each days 3 doses of 50000 units of Vitamin D made by Zahravi company

**Category**

Treatment - Drugs

**Recruitment centers**

**1**

**Recruitment center**

**Name of recruitment center**

Shahid Mdares Hospital

**Full name of responsible person**

Mahnoosh Foroughi

**Street address**

Yadegare Imam Highway- Saadat Abad St.

**City**

Tehran

**Province**

Tehran

**Postal code**

7895465489

**Phone**

+98 21 2207 4087

**Email**

mahnoosh.foroughi@gmail.com

**Sponsors / Funding sources**

**1**

**Sponsor**

**Name of organization / entity**

Shahid Beheshti University of Medical Sciences

**Full name of responsible person**

Dr.Seyed Ali Ziyaei

**Street address**

School of Medicine, Koodakyar St. Danshjoov Blv,  
Velenjak, Shahid Chamran Highway, Tehran, Iran

**City**

Tehran

**Province**

Tehran

**Postal code**

1153733163

**Phone**

+98 21 2243 9948

**Email**

erfan.tasdighi@gmail.com

**Grant name****Grant code / Reference number****Is the source of funding the same sponsor organization/entity?**

Yes

**Title of funding source**

Shahid Beheshti University of Medical Sciences

**Proportion provided by this source**

100

**Public or private sector**

Public

**Domestic or foreign origin**

Domestic

**Category of foreign source of funding**

*empty*

**Country of origin****Type of organization providing the funding**

Academic

**Person responsible for general inquiries****Contact****Name of organization / entity**

Shahid Beheshti University of Medical Sciences

**Full name of responsible person**

Erfan Tasdighi

**Position**

Medical student in Shahid Beheshti medical university

**Latest degree**

A Level or less

**Other areas of specialty/work**

General Surgery

**Street address**

Velenjak-Daneshju squer -Daneshju street-Shahid beheshti medical university

**City**

Tehran

**Province**

Tehran

**Postal code**

8781264569

**Phone**

+98 21 23871

**Email**

erfan.tasdighi@gmail.com

**Person responsible for scientific****inquiries****Contact****Name of organization / entity**

Shahid Beheshti University of Medical Sciences

**Full name of responsible person**

Mahnoosh Foroughi

**Position**

Associate professor in Shahid Beheshti medical university

**Latest degree**

Subspecialist

**Other areas of specialty/work**

General Surgery

**Street address**

Tehran Province, Tehran, District 2, Saadat Abad Boulevard

**City**

Tehran

**Province**

Tehran

**Postal code**

5264987565

**Phone**

+98 21 2207 4092

**Email**

mahnoosh.foroughi@gmail.com

**Person responsible for updating data****Contact****Name of organization / entity**

Shahid Beheshti University of Medical Sciences

**Full name of responsible person**

Erfan Tasdighi

**Position**

Medical student Shahid beheshti medical university

**Latest degree**

A Level or less

**Other areas of specialty/work**

General Surgery

**Street address**

School of Medicine, Koodakyar St. Danshjoov Blv,  
Velenjak, Shahid Chamran Highway, Tehran, Iran

**City**

Tehran

**Province**

Tehran

**Postal code**

1234567896

**Phone**

+98 21 23871

**Email**

erfan.tasdighi@gmail.com

**Sharing plan****Deidentified Individual Participant Data Set (IPD)**

Yes - There is a plan to make this available

**Study Protocol**

Yes - There is a plan to make this available

**Statistical Analysis Plan**

Yes - There is a plan to make this available  
**Informed Consent Form**  
Yes - There is a plan to make this available  
**Clinical Study Report**  
Yes - There is a plan to make this available  
**Analytic Code**  
Yes - There is a plan to make this available  
**Data Dictionary**  
Yes - There is a plan to make this available  
**Title and more details about the data/document**  
All of the information  
**When the data will become available and for how long**  
starting 6 months after publication

**To whom data/document is available**  
researcher and artisans  
**Under which criteria data/document could be used**  
Just for researcher in a same field and for pharmaceutical companies to see whether they should a drug produce and or import  
**From where data/document is obtainable**  
Cardiac surgery research center in Shahid Modarres hospital Dr.Mahnoosh Foroughi Erfan Tasdighi researcher  
Email: erfan.tasdighi@gmail.com  
**What processes are involved for a request to access data/document**  
We will decide to accept or reject the application after a session in research center  
**Comments**