Clinical Trial Protocol
Iranian Registry of Clinical Trials

18 Sep 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

Determinate 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 assign by a computerized software into two groups.After the intervention ,we will measure Apoptosis indicators including: Capase 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 immunohistochemistery (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.Patienst 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)

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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.
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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
Immunohistochemstry

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
Immunohistochemistery

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
Immunohistochemistery

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 lung 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
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Sponsors / Funding sources

1

Sponsor
Name of organization / entity
Shahid Beheshti University of Medical Sciences
Full name of responsible person
Dr.Seyed Ali Ziyaei

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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
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
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A Level or less
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Person responsible for updating data

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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