Clinical Trial Protocol
Iranian Registry of Clinical Trials

18 Sep 2026

Effect of Treating Vitamin D Deficiency on Postoperative Atrial Fibrillation after Coronary Artery Bypass Surgery: A Double Blinded Randomized Controlled Trial

Protocol summary

Study aim

1) assessing vitamin d level before surgery in controlled and intervention group 2) assessing occurrence of atrial fibrillation after the surgery 3) assessing number of attacks after the surgery 4) assessing requiring any drug for atrial fibrillation after the surgery

Design

parallel randomized placebo-controlled double blinded clinical trial with 400 participants with vitamin d deficiency

Settings and conduct

by taking a blood sample we will evaluate the inclusion and exclusion criteria, then an echocardiography will assess the valvular problems and the left ventricular function of the heart. the patients will randomly allocated into two groups in which placebo and active drug will use. the holik's protocol conducted for the 8 weeks before the surgery and then right before the surgery another blood sample and an echocardiography will show us the differences in these 8 weeks after that the cabg perform by one surgeon and the same operation team. after that the patient go to the ICU as a routine procedure and during that they are under full 24hours monitoring and if the specific nurse sees any changes in lead 2 of the monitor, she will take a 12 lead electrocardiography which will interpreted for atrial fibrillation. the atrial fibrillation is defined as irregular heart rhythm with tachycardia in which p waves do not have equal distance fro each other.

Participants/Inclusion and exclusion criteria

inclusion criteria: 1) hypovitaminisis d 2) tent to participate in this project 3) aged 40-70 4) have cabg surgery indications like occlusion of three vessels not including in this study criteria: 1) having atrial fibrillation before or consuming any drug for that 2) normal level vitamin d 3) not to tend in this project 4) have any valvular problem 5) hyperparathyroidism 6) thyroid dysfunction 7) chronic obstructive pulmonary disease 8) liver failure 9) renal failure 10) having any cancer exclusion criteria: 1) vitamin d toxicity 2) hypercalcemia 3) decreased renal function during the project 4) morbid obesity

Intervention groups

In this study we will treat vitamin D deficiency under Holick’s protocol using 50,000 IU of Vitamin D3 (cholecalciferol) every week for 8 weeks to achieve the sufficient level (30<25(OH) Vitamin D<80) and then 50,000 IU every month (4weeks) till the end of the study. Vitamin D3 (cholecalciferol) will be bought from pharmaceutical company.

Main outcome variables

atrial fibrillation occurrence after CABG, number of attacks, whether they need drug for atrial fibrillation, ejection fraction of the heart and left ventricular end diastolic volume according to pre and post op echocardiography

General information

Reason for update

Acronym

VIDAF

IRCT registration information

IRCT registration number: **IRCT20170620034666N1**
Registration date: **2018-03-05, 1396/12/14**
Registration timing: **prospective**

Last update: **2018-03-05, 1396/12/14**
Update count: **0**

Registration date

2018-03-05, 1396/12/14

Registrant information

Name

Mehran Shahzamani

Name of organization / entity

Isfahan university of medical science
Country
Iran (Islamic Republic of)
Phone
+98 31 3670 1227
Email address
m.shahzamani@med.mui.ac.ir

Recruitment status
Recruitment complete
Funding source

Expected recruitment start date
2018-04-04, 1397/01/15
Expected recruitment end date
2020-04-03, 1399/01/15
Actual recruitment start date
empty
Actual recruitment end date
empty
Trial completion date
empty

Scientific title
Effect of Treating Vitamin D Deficiency on Postoperative Atrial Fibrillation after Coronary Artery Bypass Surgery: A Double Blinded Randomized Controlled Trial

Public title
Treating Vitamin D Deficiency on Post CABG Atrial Fibrillation
Purpose
Prevention
Inclusion/Exclusion criteria
Inclusion criteria:
b) Hypovitaminosis D (serum 25(OH) Vitamin D< 20 ng/ml) c) Written and informed consent to participate in this project CABG indications like trivessel occlusion no emergency intervention needed
Exclusion criteria:
e) Hyperparathyroidism (PTH>upper normal limit according to lab reference range) f) Liver failure (any positive past medical history or AST and/or ALT 2 times more than normal upper limit) g) Renal Failure (any positive past medical history or Glomerular filtration rate <60 calculated with MDRD eGFR formula of Qx medical application) h) Any prior history of diagnosed cancer, rheumatologic and immunologic disorders b) BMI>30 kg/m2 vitamin d toxicity hypercalcemia
Age
From **30 years** old to **70 years** old
Gender
Both

Phase
2
Groups that have been masked

- Participant
- Care provider
- Investigator

Sample size
Target sample size: **400**

Randomization (investigator's opinion)
Randomized
Randomization description
consecutive sampling is applicable in clinic in which we want to choose the participant, the surgeon evaluates the inclusion and exclusion criteria then by using a Random bottom of calculator, the last number at right will be chosen, if it is even the patient go to group A, and if it is odd the patient go to the group B, then the next patient will be the reverse and this process repeated for each 2 patients and this will allocated patients in 2 group of equal number of patients.
Blinding (investigator's opinion)
Double blinded
Blinding description
This study will conducted under double blinded manner in which both patients and researchers will be blinded about the placebo and drug groups until completing the study. The placebo will be identical as the drug and the pharmaceutical company will provide this for us.
Placebo
Used
Assignment
Parallel
Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee
Name of ethics committee
Isfahan University of Medical Sciences; Medical Ethics Board Committee
Street address
hezar jarib blvd.
City
ISFAHAN
Province
Isfehan
Postal code
81746-73461
Approval date
2017-12-18, 1396/09/27
Ethics committee reference number
IR.MUI.REC.1396.1.140

Health conditions studied

1

Description of health condition studied
ICD-10 code
ICD-10 code description

2

Description of health condition studied

vitamin d deficiency

ICD-10 code

E55.9

ICD-10 code description

Vitamin D deficiency, unspecified

3

Description of health condition studied

atrial fibrillation after the surgery

ICD-10 code

I48

ICD-10 code description

Atrial fibrillation and flutter

Primary outcomes

1

Description

occurrence of atrial fibrillation after the surgery

Timepoint

till 7 days after the surgery 24 hours in ICU

Method of measurement

electrocardiography

2

Description

number of atrial fibrillation

Timepoint

till 7 days after the surgery 24 hours in ICU

Method of measurement

electrocardiography

3

Description

left ventricular function

Timepoint

before starting taking drugs, before surgery, before discharging from hospital

Method of measurement

echocardiography

Secondary outcomes

1

Description

left ventricular function after 1 year

Timepoint

before starting taking drugs, before surgery, before discharge and 1 year after the surgery

Method of measurement

echocardiography

Intervention groups

1

Description

Intervention group: receiving vitamin d active drug

Category

Treatment - Drugs

2

Description

Control group: receiving placebo

Category

Treatment - Drugs

Recruitment centers

1

Recruitment center

Name of recruitment center

cardiac surgery clinic of chamran heart center

Full name of responsible person

mehran shahzamani

Street address

3rd moshtagh st.

City

isfahan

Province

Isfehan

Postal code

8174673461

Phone

+98 31 3667 1832

Email

m.shahzamani@med.mui.ac.ir

Sponsors / Funding sources

1

Sponsor

Name of organization / entity

isfahan university of medical sciences

Full name of responsible person

research department of isfahan universiry of medical sciences

Street address

hezar jarib blvd.

City

isfahan

Province

Isfehan

Postal code

8174673461

Phone

+98 31 3668 0048

Email

m.shahzamani@med.mui.ac.ir

Grant name

Grant code / Reference number

Is the source of funding the same sponsor organization/entity?

Yes

Title of funding source

isfahan 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
Isfahan University of Medical Sciences
Full name of responsible person
Mehran Shahzamani
Position
assistant professor
Latest degree
Subspecialist
Other areas of specialty/work
cardiac surgery
Street address
Isfahan-hezar jerib st
City
Isfahan
Province
Isfehan
Postal code
81746-73461
Phone
+98 31 3670 1227
Fax
+98 31 3670 1227
Email
m.shahzamani@med.mui.ac.ir

Person responsible for scientific inquiries

Contact
Name of organization / entity
Isfahan University of Medical Sciences
Full name of responsible person
Mehran Shahzamani
Position
assistant professor
Latest degree
Subspecialist
Other areas of specialty/work
cardiac surgery
Street address
Isfahan-hezar jerib st
City
Isfahan
Province
Isfehan
Postal code
81746-73461
Phone
+98 31 3670 1227
Fax
+98 31 3670 1227
Email
m.shahzamani@med.mui.ac.ir

Person responsible for updating data

Contact
Name of organization / entity
Isfahan University of Medical Sciences
Full name of responsible person
Mehran Shahzamani
Position
assistant professor
Latest degree
Subspecialist
Other areas of specialty/work
cardiac surgery
Street address
Isfahan-hezar jerib st
City
Isfahan
Province
Isfehan
Postal code
81746-73461
Phone
+98 31 3670 1227
Fax
+98 31 3670 1227
Email
m.shahzamani@med.mui.ac.ir

Sharing plan

Deidentified Individual Participant Data Set (IPD)
Yes - There is a plan to make this available
Study Protocol
Undecided - It is not yet known if there will be a plan to make this available
Statistical Analysis Plan
Undecided - It is not yet known if there will be a plan to make this available
Informed Consent Form
Undecided - It is not yet known if there will be a plan to make this available
Clinical Study Report
Undecided - It is not yet known if there will be a plan to make this available
Analytic Code
Undecided - It is not yet known if there will be a plan to make this available
Data Dictionary
Undecided - It is not yet known if there will be a plan to make this available
Title and more details about the data/document
we just publish our protocol and analyzed result for publication
When the data will become available and for how long

2020

To whom data/document is available

mehran shahzamani

Under which criteria data/document could be used

from published article

From where data/document is obtainable

2019

What processes are involved for a request to access data/document

email

Comments