Clinical Trial Protocol
Iranian Registry of Clinical Trials

18 Sep 2026

Effect of Preoperative Vitamin D Supplementation on Atrial Fibrillation Incidence After Coronary Artery Bypass Graft

Protocol summary

Study aim

Investigating the effect of vitamin D supplementation before surgery on the occurrence of atrial fibrillation after coronary artery bypass surgery

Design

The present study is a clinical trial phase 3, on 246 patients, with parallel and double-blind randomized groups, with a control group. Block randomization method will be used.

Settings and conduct

This study will be conducted in Modares Hospital in Tehran. The study will be done in a double-blind manner in terms of the interventionist and the analyst. Patients with vitamin D deficiency will randomly divided into 2 control and intervention groups. After surgery, during hospitalization, the patients will be examined for the occurrence of atrial fibrillation, and finally, 2 groups will be compared for the occurrence of atrial fibrillation.

Participants/Inclusion and exclusion criteria

entrance criteria: having Vitamin D deficiency; being a candidate for CABG; having consent to participate in the study. Exclusion criteria: Presence of atrial fibrillation before surgery; Receiving anti-arrhythmic drugs (except Beta Blocker); Pace maker employment record; Off pump CABG surgery; Redo surgery; History of receiving vitamin D and calcium supplements

Intervention groups

1st group: the group receiving vitamin D; from 3 days before the surgery, they receive a daily dose of oral vitamin D supplement in the form of 150000 units (3 doses of 50000 units in the morning, noon and night) and a total of 450000 units. 2nd group: the group receiving the placebo; from 3 days before the surgery, exactly with the process of the first group, receive placebo.

Main outcome variables

occurrence of atrial fibrillation

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20230506058103N1**
Registration date: **2023-05-20, 1402/02/30**
Registration timing: **prospective**

Last update: **2023-05-20, 1402/02/30**
Update count: **0**

Registration date

2023-05-20, 1402/02/30

Registrant information

Name

arezoo hayatimoghadam

Name of organization / entity

Country

Iran (Islamic Republic of)

Phone

+98 21 4427 1889

Email address

arezoo_hyti_27@yahoo.com

Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2023-07-23, 1402/05/01

Expected recruitment end date

2024-02-19, 1402/11/30

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Effect of Preoperative Vitamin D Supplementation on Atrial Fibrillation Incidence After Coronary Artery Bypass Graft

Public title
effect of vitamin D in incidence of atrial fibrillation
Purpose
Prevention
Inclusion/Exclusion criteria
Inclusion criteria:
presence of Vitamin D deficiency Being a candidate for coronary artery bypass graft surgery Consent to participate in the study
Exclusion criteria:
history of atrial fibrillation before surgery receiving antiarrhythmic drugs (except beta blockers) history of chronic obstructive pulmonary disease Pacemaker brokerage experience history of renal failure hypercalcemia history of kidney stone history of emergency surgeries History of multiple surgeries history of hyperthyroidism history of sarcoidosis History of malabsorption syndrome History of bleeding and tamponade History of off pump coronary artery bypass grafting redo surgery History of receiving vitamin D and calcium supplements
Age
No age limit
Gender
Both

Phase
3
Groups that have been masked

- Participant
- Care provider
- Outcome assessor
- Data analyser

Sample size
Target sample size: **246**
Randomization (investigator's opinion)
Randomized
Randomization description
The randomization will be done using a block method (4 patients in each block). At first, the patients will be divided into groups of four according to the time of entry into the study, and the list of groups will be randomly divided into two lists A and B using random.org. The intervention receiving group will be determined based on a coin toss. Also, the stages of the study are performed in a double-blind manner in terms of the patients, the interventionist and the analyst. Randomization and enrollment of patients into two groups will be done by a third party (secretary of cardiac surgery department) and the patients, the main researchers and the data analyst will not be aware of the randomization result.
Blinding (investigator's opinion)
Double blinded
Blinding description
Patients, outcome assessors and clinical caregivers will not be informed of the randomization result. Randomization and enrollment of patients into two groups will be done by a third party (secretary of cardiac surgery department) and the patients, the main researchers and the data analyst will not be aware of the randomization result. The data presented to the data analyst will be anonymous.
Placebo
Used
Assignment
Parallel
Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee
Name of ethics committee
Medical School ethics committee of shahid beheshti university of medical sciences
Street address
daneshjoo Blvd., velenjak, tehran
City
Tehran
Province
Tehran
Postal code
193954739
Approval date
2022-10-23, 1401/08/01
Ethics committee reference number
IR.SBMU.MSP.REC.1401.356

Health conditions studied

1

Description of health condition studied
atrial fibrillation
ICD-10 code
I48
ICD-10 code description
Atrial fibrillation and flutter

Primary outcomes

1

Description
Percentage of people with atrial fibrillation
Timepoint
incidence of atrial fibrillation During hospitalization after Coronary artery bypass grafting
Method of measurement
Monitoring the patient's electrocardiogram

Secondary outcomes

empty

Intervention groups

1

Description
Intervention group: Patients receiving vitamin D: The intervention group, starting 3 days before the surgery, will receive a daily dose of vitamin D supplements in the form of 150 thousand units (3 doses of 50 thousand units in the morning, noon and night) and a total of 450 thousand units.
Category
Treatment - Drugs

2

Description
Control group: patients receiving placebo: Patients in the placebo group will receive a placebo similar to the original drug, similar to the intervention group (starting three days before surgery and three times a day).
Category
Placebo

Recruitment centers

1

Recruitment center
Name of recruitment center
Modarres hospital
Full name of responsible person
Arezoo Hayatimoghaddam
Street address
Saadatabad Blvd., Saadatabad, Tehran, Iran
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Province
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Postal code
1998733383
Phone
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Email
modarres@sbmu.ac.ir
Web page address
https://modarres.sbmu.ac.ir/

Sponsors / Funding sources

1

Sponsor
Name of organization / entity
Shahid Beheshti University of Medical Sciences
Full name of responsible person
Afshin Zarghi
Street address
Shahid Beheshti University of Medical Sciences, Arabi St., Student Blvd., Valenjak, Tehran
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Province
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Postal code
1985717443
Phone
+98 21 23871
Email
info@sbmu.ac.ir
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
Arezoo Hayatimoghaddam
Position
internal medicine resident
Latest degree
Medical doctor
Other areas of specialty/work
Internal Medicine
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Medical doctor
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Person responsible for updating data

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Sharing plan

Deidentified Individual Participant Data Set (IPD)
No - There is not a plan to make this available
Justification/reason for indecision/not sharing IPD
The data will remain confidential with the researcher; Other researchers will receive de-identified personal data of the participants by sending an email to the principal investigator if they provide a valid reason for needing the data of this study.
Study Protocol
No - There is not a plan to make this available
Statistical Analysis Plan
No - There is not a plan to make this available
Informed Consent Form
No - There is not a plan to make this available
Clinical Study Report
Yes - There is a plan to make this available
Analytic Code
No - There is not a plan to make this available
Data Dictionary
No - There is not a plan to make this available
Title and more details about the data/document
The data will remain confidential with the researcher; Other researchers will receive de-identified personal data of the participants by sending an email to the principal investigator if they provide a valid reason for needing the data of this study.
When the data will become available and for how long
The start of the data access period will be 12 months after the publication of the results.
To whom data/document is available
The data will only be available to researchers working in academic and scientific institutions.
Under which criteria data/document could be used
Data will be sent to the researchers of reputable academic and scientific institutions, with the presentation of justified evidence, only for conducting scientific and research studies.
From where data/document is obtainable
Researchers can contact the main researcher through the email address below. Arezoo_Hyti_27@yahoo.com
What processes are involved for a request to access data/document
After receiving the e-mail related to the request and after studying the proofs and documents provided by the requester, the main researcher will inform the complainant about the approval or disapproval of the request within 1 week. If the request is approved, the data will be sent via email along with the confirmation email.
Comments