Clinical Trial Protocol
Iranian Registry of Clinical Trials

16 Sep 2026

: Prophylactic effect of vitamin D supplementation in the prevention of atrial fibrillation after coronary artery bypass grafting : Randomized Clinical Trial

Protocol summary

Study aim
Prophylactic effect of vitamin D supplementation in the prevention of atrial fibrillation after coronary artery bypass grafting(CABG) : Randomized Clinical Trial

Design
Clinical trial with 3 parallel groups, double blind, randomised, phase 2 on 90 patients, in block randomization method with the size of 4 and 6, Random sequence will be generated by an epidemiologist by running an online program in sealed envelope website (https://www.sealedenvelope.com/).

Settings and conduct
The aim of the study is evaluation of prophylactic effect of vitamin D supplementation in the prevention of atrial fibrillation after coronary artery bypass grafting in 90 patients of Amiralmomenin hospital in Arak city.In group A 300000 IU of vit D, in group B 480000 IU and in group C 600000 IU of vit C (equivalent of 2 cc vial), will be given to the patients 72 hours before the surgery.

Participants/Inclusion and exclusion criteria
Inclusion criteria: Patients who are condidated for elective CABG that have informed consent for joining to the study. All patients that duration of their surgery is less than 6 hours. Serum level of vit D less than 30 nanomol per litr Non inclusion criteria: History of having arrhythmia and atrial fibrillation History of using antiarrhythmic drugs in class I and III or Digoxin History of having permanent or temporary pace maker History of atrioventricular block or bradycardia with less than 50 heart beat per minute History of severe kidney or pulmonary or liver disease Non elective CABG Patients who need heart valve replacement surgery, too

Intervention groups
In group A 300000 IU of vit D (equivalent of 2 cc of 300000 IU vial), in group B 480000 IU (equivalent of 2 cc of 480000 IU vial) and in group C 600000 IU of vit D (equivalent of 2 cc of 600000 IU vial), will be given to the patients 72 hours before the surgery.

Main outcome variables
Frequency of post CABG atrial fibrillation

General information

Reason for update

Acronym

IRCT registration information
IRCT registration number: **IRCT20201028049175N4**
Registration date: **2021-01-16, 1399/10/27**
Registration timing: **prospective**

Last update: **2021-01-16, 1399/10/27**
Update count: **0**

Registration date
2021-01-16, 1399/10/27

Registrant information

Name
Shamim Valibak

Name of organization / entity

Country
Iran (Islamic Republic of)

Phone
+98 86 3417 3502

Email address
sh.valibak@yahoo.com

Recruitment status
Recruitment complete

Funding source

Expected recruitment start date
2021-01-29, 1399/11/10

Expected recruitment end date
2022-12-01, 1401/09/10

Actual recruitment start date
empty

Actual recruitment end date
empty
Trial completion date
empty

Scientific title
: Prophylactic effect of vitamin D supplementation in the prevention of atrial fibrillation after coronary artery bypass grafting : Randomized Clinical Trial

Public title
: Prophylactic effect of vitamin D supplementation in the prevention of atrial fibrillation after coronary artery bypass grafting : Randomized Clinical Trial
Purpose
Prevention
Inclusion/Exclusion criteria
Inclusion criteria:
Patients who are condidated for elective CABG that have informed consent for joining to the study. All patients that duration of their surgery is less than 6 hours. Serum level of vit D less than 30 nanomol per litr
Exclusion criteria:
History of having arrhythmia and atrial fibrillation History of using antiarrhythmic drugs in class I and III or Digoxin History of having permanent or temporary heart pace maker History of atrioventricular block or bradycardia with less than 50 heart beat per minute History of severe kidney or pulmonary (pneumonia or chronic obstractive pulmonary disease) or liver (cirrhosis or fulminant hepatitis) disease Non elective CABG Patients who need heart valve replacement surgery, in addition to CABG
Age
From **45 years** old to **80 years** old
Gender
Both

Phase
2
Groups that have been masked

- Participant
- Investigator

Sample size
Target sample size: **90**
Randomization (investigator's opinion)
Randomized
Randomization description
Patients will be allocated into two groups using a permuted balanced block randomization method with the size of blocks 4 and 6. Random sequence will be generated by an epidemiologist by running an online program in sealed envelope website (https://www.sealedenvelope.com/). Concealment is also guaranteed due to the use of specific codes that are obtained by the website.
Blinding (investigator's opinion)
Double blinded
Blinding description
All of patients and the person who will fill the check lists are unaware about dosage of the drugs and drugs will be prescripted by the anesthesiologist 72 hours before the surgery.
Placebo
Not used
Assignment
Parallel
Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee
Name of ethics committee
Ethics committee of Arak University of Medical Sciences
Street address
Assistance of research and technology, Payambare azam institution, Arak University of Medical Sciences, Basij square
City
Arak
Province
Markazi
Postal code
3848176341
Approval date
2019-06-16, 1398/03/26
Ethics committee reference number
IR.ARAKMU.REC.1398.089

Health conditions studied

1

Description of health condition studied
Atrial fibrillation after CABG
ICD-10 code
I48.0
ICD-10 code description
Paroxysmal atrial fibrillation

2

Description of health condition studied
Atrial fibrillation after CABG
ICD-10 code
T82.9
ICD-10 code description
Unspecified complication of cardiac and vascular prosthetic device, implant and graft

Primary outcomes

1

Description
Frequency of post CABG atrial fibrillation
Timepoint
From the end of surgery untill 72 hours after surgery

Method of measurement
heart monitoring

Secondary outcomes

empty

Intervention groups

1

Description
Intervention group: In group A 300000 IU of vit D (equivalent of 2 cc of 300000 IU vial) will be given to the patients 72 hours before the surgery.
Category
Prevention

2

Description
Intervention group: In group B 480000 IU of vit D (equivalent of 2 cc of 480000 IU vial) will be given to the patients 72 hours before the surgery.
Category
Prevention

3

Description
Intervention group: In group C 600000 IU of vit D (equivalent of 2 cc of 600000 IU vial) will be given to the patients 72 hours before the surgery.
Category
Prevention

Recruitment centers

1

Recruitment center
Name of recruitment center
Amiralmomenin hospital
Full name of responsible person
Alireza Kamali
Street address
Amiralmomenin hospital street, Basij square
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Sponsors / Funding sources

1

Sponsor
Name of organization / entity
Arak University of Medical Sciences
Full name of responsible person
Alireza Kamali
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Assistance of research and technology, Payambare azam institution, Arak University of Medical Sciences, Basij square
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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
Arak 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
Arak University of Medical Sciences
Full name of responsible person
Alireza Kamali
Position
lecturer
Latest degree
Specialist
Other areas of specialty/work
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Person responsible for scientific inquiries

Contact

Name of organization / entity
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Assistant professor
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Person responsible for updating data

Contact

Name of organization / entity
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General physician non-faculty
Latest degree
Medical doctor
Other areas of specialty/work
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Sharing plan

Deidentified Individual Participant Data Set (IPD)
Undecided - It is not yet known if there will be 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