

Clinical Trial Protocol

Iranian Registry of Clinical Trials

21 Jul 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 liter 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 liter

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 obstructive 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 prescribed 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

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Amiralmomenin hospital street, Basij square

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Sponsors / Funding sources**1****Sponsor****Name of organization / entity**

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Full name of responsible person

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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

Anesthesiology

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

Arak University of Medical Sciences

Full name of responsible person

Alireza Rostami

Position

Assistant professor

Latest degree

Specialist

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

Arak University of Medical Sciences

Full name of responsible person

shamim valibak

Position

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