

Clinical Trial Protocol

Iranian Registry of Clinical Trials

10 Jun 2026

Evaluating the effect of vitamin D on the prevention of postoperative atrial fibrillation following coronary artery bypass grafting (CABG) surgery

Protocol summary

Study aim

Investigate the effect vitamin D supplementation on atrial fibrillation incidence

Design

Clinical trial with control group, with parallel groups, without blinding, randomized, Phase 3 on 160 patients. Randomization is performed by statistician and random allocation of one arrangement to one block

Settings and conduct

This trial is held in Tehran heart center. Included patients are randomly divided into two groups. One group receives 600000IU cholecalciferol pearl. Patients are monitored for the occurrence of atrial fibrillation after surgery for 5 days

Participants/Inclusion and exclusion criteria

Inclusion criteria: Patients older than 18 years who are to undergo CABG surgery with 25 hydroxy vitamin D levels less than 30ng/ml and a stable hemodynamic. Exclusion criteria: Concurrent valvular surgery, redo surgery, emergency CABG, history of supraventricular arrhythmia, use of anti arrhythmic drugs except for beta blockers, digoxin and calcium channel antagonists, current use of any vitamin D or magnesium supplement, drugs affecting vitamin D metabolism, hypercalcemia, history of cholecalciferol hypersensitivity, chronic kidney disease, chronic liver disease

Intervention groups

Patients are divided into two groups. One group receives 600000IU cholecalciferol pearl in addition to routine cares of CABG surgery candidates and the other group just receives the routine care of CABG patients.

Main outcome variables

Occurrence of POAF during the first 5 days after surgery

General information

Reason for update

To Complete study information.

Acronym

IRCT registration information

IRCT registration number: **IRCT201511298698N16**

Registration date: **2016-05-21, 1395/03/01**

Registration timing: **registered_while_recruiting**

Last update: **2020-07-23, 1399/05/02**

Update count: **1**

Registration date

2016-05-21, 1395/03/01

Registrant information

Name

Azita Hajhossein Talasaz

Name of organization / entity

Department of Clinical Pharmacy, Faculty of Pharmacy, Tehran University of Medical Sciences

Country

Iran (Islamic Republic of)

Phone

+98 66954709

Email address

atalasaz@razi.tums.ac.ir

Recruitment status

Recruitment complete

Funding source

Pharmacy faculty

Expected recruitment start date

2016-04-08, 1395/01/20

Expected recruitment end date

2017-02-28, 1395/12/10

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Evaluating the effect of vitamin D on the prevention of postoperative atrial fibrillation following coronary artery bypass grafting (CABG) surgery

Public title

The effect of vitamin D on AF after CABG surgery

Purpose

Prevention

Inclusion/Exclusion criteria

Inclusion criteria:

Patient is older than 18 years old Patient is vitamin D deficient (<30ng/ml) Patient is to undergo CABG surgery Patient has a stable hemodynamic

Exclusion criteria:

Concurrent valvular surgery History of supraventricular arrhythmias Use of anti arrhythmic drugs except beta blockers,calcium channel blochers or digital compounds Use of drugs affecting vitamin D metabolism Hypercalcemia History of allergy to cholecalciferol Emergency CABG surgery Chronic liver disease Chronic kidney disease Current use of vitamin D supplement Redo CABG surgery Current use of Mg supplement

Age

From **18 years** old

Gender

Both

Phase

3

Groups that have been masked

No information

Sample size

Target sample size: **160**

Randomization (investigator's opinion)

Randomized

Randomization description

Randomization is performed with Permuted block randomization method by statistician. Statistician determines the possible arrangements of blocks of size of 4 for patients. Randomly one arrangement is chosen for each block.

Blinding (investigator's opinion)

Not blinded

Blinding description

Placebo

Not used

Assignment

Parallel

Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee

Ethics committee of Tehran University of Medical Sciences

Street address

4th floor, NO.23, 16 Azar st. , Keshavarz Blvd.

City

Tehran

Province

Tehran

Postal code

1417653761

Approval date

2016-01-11, 1394/10/21

Ethics committee reference number

IR.TUMS.REC.1394.1617

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

Atrial fibrillation

Timepoint

After CABG for 5 days

Method of measurement

ECG

2

Description

CRP

Timepoint

Daily for 5days

Method of measurement

laboratory

Secondary outcomes

1

Description

ICU stay

Timepoint

Time of transfer to ward

Method of measurement

days

2

Description

Hospital stay

Timepoint

Length of hospital stay
Method of measurement
days

Intervention groups

1

Description
600000 IU oral vit D3 (3-5 days before surgery)
Category
Treatment - Drugs

2

Description
The patient did not receive any intervention
Category
Other

Recruitment centers

1

Recruitment center
Name of recruitment center
Tehran Heart Center
Full name of responsible person
Maryam Daei
Street address
Tehran Heart Center.next to Shariati hospital, north
Karegar street
City
Tehran
Province
Tehran
Postal code
1417653761
Phone
+98 21 8802 9242
Email
atalasaz@razi.tums.ac.ir

Sponsors / Funding sources

1

Sponsor
Name of organization / entity
Tehran University of Medical Sciences
Full name of responsible person
Dr. Ahmad Esmaeizadeh
Street address
Vice chancellor, 6th floor, university central
organisation, next to Ghods Street, Keshavarz
boulevard
City
Tehran
Province
Tehran
Postal code
1417653761

Phone
+98 21 8895 3019
Email
ic-research@tums.ac.ir

Grant name
Grant code / Reference number
**Is the source of funding the same sponsor
organization/entity?**
Yes
Title of funding source
Tehran 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
Tehran University of Medical Sciences
Full name of responsible person
Maryam Daei
Position
Clinical pharmacy
Latest degree
Specialist
Other areas of specialty/work
clinical pharmacy
Street address
Clinical pharmacy department, pharmacy faculty, 16
Azar street, Keshavarz boulevard
City
Tehran
Province
Tehran
Postal code
1417653761
Phone
+98 912 337 9653
Fax
Email
marydaei@yahoo.com
Web page address

Person responsible for scientific inquiries

Contact
Name of organization / entity
Tehran university of medical sciences
Full name of responsible person
Dr.Azita Hajhossein Talasaz
Position
Assistant Professor, Pharm D, BCPS

Latest degree

Specialist

Other areas of specialty/work**Street address**

Tehran Heart Center, next to Shariati hospital, north Karegar,

City

Tehran

Province

Tehran

Postal code

1417653761

Phone

+98 21 8802 9242

Fax**Email**

ahhtalasaz@razi.tums.ac.ir

Web page address

+98 21 8802 9242

Fax**Email**

marydaei@yahoo.com

Web page address**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

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

Yes - There is a plan to make this available

Analytic Code

Not applicable

Data Dictionary

Not applicable

Title and more details about the data/document

The information about primary outcome can be shared

When the data will become available and for how long

After publication

To whom data/document is available

Researchers working in academic institutions

Under which criteria data/document could be used

The user should send his/her request for Dr. Talasaz

From where data/document is obtainable

Dr Azita Haj Hossein Talasaz Tehran Heart Center- North Karegar- Tehran

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

The applicant posts his/her requested information for Dr. Talasaz. Dr Talasaz sends her reply after investigating the request and after a maximum of 3 months.

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

Pharmacy Faculty

Full name of responsible person

Maryam Daei

Position

Resident

Latest degree

Medical doctor

Other areas of specialty/work

Clinical Pharmacy

Street address

Clinical pharmacy department, Pharmacy Faculty, 16 Azar street, Keshavarz boulevard

City

Tehran

Province

Tehran

Postal code

1417653761

Phone