Clinical Trial Protocol
Iranian Registry of Clinical Trials

17 Sep 2026

The association between vitamin D medication therapy and reducing post coronary bypass graft surgery acute kidney injury in patients with low vitamin D levels.

Protocol summary

Study aim

Evaluation the effect of vitamin D prescription on early complications of CABG surgery such as AKI by KIM-1 , IL-18urinary levels.

Design

Interventional clinical trial has controll and intervention groups,parallel group trial,randomization was computerized,clinical trial is double blind and community based.

Settings and conduct

Method of randomization is simple .unit of randomization is individual. The tool of randomization is computer software.this study is double blinded and the participants in study,care providers, investigators and data analysers are blinded.study is about connection between vitamin D level and CS-AKI in patients is going to have CABG in modarres hospital measured by IL18,KIM1 urinary levels.

Participants/Inclusion and exclusion criteria

inclusion criteria: 1.CABG surgery for the first time. 2.The patient who has just CABG surgery without another surgery like valvular replacement at the same time. 3.CPB usage in surgery. 4.Patients with vitamin D level less than 20 ng/m. exclusion criteria: 1.Taking vitamin D supplement. 2.ESRD or cr level more than 1.5 mg/dl. 3.Taking nephrotoxic drugs. 4.Less than 3 days gap between angiography and surgery.

Intervention groups

We designed 2 groups: 1. intervention group . 2. observation group. In intervention group ,we prescribed pearl vitamin D 50000 units 3 times a day for 3 days before the surgery . in observation group we prescribed placebo instead of vitamin D in similarly.

Main outcome variables

1.The renal markers' (IL-18,KIM-1) changes under the effect of vitamin D as a protective subject. 2. vitamin D effect on bleeding in no time , 6 hours , 12 hours after surgery 3. vitamin D effect on ventilation after CABG surgery . 4.vitamin D effect on transfusion after CABG surgery. 5.Creatinine levelsin no time before the surgery, after surgery and the day after surgery.

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20180131038578N1**
Registration date: **2019-03-20, 1397/12/29**
Registration timing: **registered_while_recruiting**

Last update: **2019-03-20, 1397/12/29**
Update count: **0**

Registration date

2019-03-20, 1397/12/29

Registrant information

Name

Pegah Eslami

Name of organization / entity

Country

Iran (Islamic Republic of)

Phone

+98 21 4609 4291

Email address

pegahslm@gmail.com

Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2019-01-21, 1397/11/01

Expected recruitment end date

2019-06-22, 1398/04/01

Actual recruitment start date

2019-01-21, 1397/11/01

Actual recruitment end date
2019-06-22, 1398/04/01
Trial completion date
empty

Scientific title
The association between vitamin D medication therapy and reducing post coronary bypass graft surgery acute kidney injury in patients with low vitamin D levels.

Public title
The effect of preoperative and postoperative vitamin D medication therapy on postoperative urinary IL18,KIM1levels in modarres hospital CABG patients in 1397 year
Purpose
Health service research
Inclusion/Exclusion criteria
Inclusion criteria:
CABG surgery for the first time. The patient who had just CABG surgery without another surgery at the same time, like valvular replacement. CPB usage in the surgery. Patients with vitamin D level less than 20 ng/ml.
Exclusion criteria:
Taking vitamin D supplements before the study. ESRD or cr level more than 1.5 mg/dl Taking nephrotoxic drugs. Less than 3 days gap between angiography and surgery.
Age
From **18 years** old to **80 years** old
Gender
Both

Phase
1
Groups that have been masked

- Participant

Sample size
Target sample size: **66**
More than 1 sample in each individual
Number of samples in each individual: **4**
We will have 4 samples for measurement of IL18,KIM1 of each member: 1. Before surgery (basic). 2.in the operation room. 3.After surgery. 4.first day after surgery.
Actual sample size reached: **66**
More than 1 sample in each individual
Actual sample size in each individual: **4**
We have 4 samples of each member:1. Before surgery measurement of IL18,KIM1 (basical) 2.in the OR at the same time of surgery for IL18,KIM1 measurement . 3.After surgery 4.first day after surgery
Randomization (investigator's opinion)
Randomized
Randomization description
Method of randomization is simple .unit of randomization is individual. The tool of randomization is computer software.
Blinding (investigator's opinion)
Double blinded
Blinding description
This study is double blinded and the participants in study,care providers, investigators and data analysers are blinded.
Placebo
Used
Assignment
Parallel
Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee
Name of ethics committee
Ethics committe of shahid beheshti university of medical sciences
Street address
Velenjak St. , Shahid Chamran Highway
City
Tehran
Province
Tehran
Postal code
1985717443
Approval date
2019-01-15, 1397/10/25
Ethics committee reference number
IR.SBMU.MSP.REC.633

Health conditions studied

1

Description of health condition studied
Post coronary artery bypass graft surgery acute kidney injury
ICD-10 code
N99.0
ICD-10 code description
Postprocedural (acute) (chronic) kidney failure

Primary outcomes

1

Description
The renal injury marker urinary level interlukin-18.
Timepoint
Before the surgery, in no time after surgery , a day after surgery.
Method of measurement
The enzyme-linked immunosorbent assay (ELISA)

2

Description
The renal injury marker urinary level,kidney injury molecule-1.
Timepoint
Before the surgery, in no time after surgery , a day after

surgery.

Method of measurement

The enzyme-linked immunosorbent assay (ELISA).

Secondary outcomes

1

Description

Bleeding .

Timepoint

In no time , 6 hours , 12 hours after surgery 2.

Method of measurement

Collected by chest tube by ML/Hour

2

Description

Ventilation .

Timepoint

During 12 hours after CABG surgery.

Method of measurement

Ventilator for ventilation measuring by per hour

3

Description

Packed RBC cell transfusion .

Timepoint

During 12 hours after CABG surgery .

Method of measurement

packed RBC cell bag for transfusion.

4

Description

Creatinine serum levels .

Timepoint

In no time before the surgery, after surgery and the day after surgery.

Method of measurement

Laboratory test for creatinine.

Intervention groups

1

Description

Intervention group: is going to be prescribed 50000 units vitamin D for 3 consecutive days , 3 times a day. vitamin D level ,IL18,KIM1is going to be measured before the surgery.IL18,KIM1is going to be measured during the surgery, the day after surgery in both groups

Category

Prevention

2

Description

Control group: is going to be prescribed placebo for 3 consecutive days , 3 times a day,vitamin D level ,IL18,KIM1is going to be measured before the surgery.IL18,KIM1is going to be measured during the surgery, the day after surgery

Category

Prevention

Recruitment centers

1

Recruitment center

Name of recruitment center

Modarres hospital

Full name of responsible person

Mahnoosh Foroughi

Street address

District 2,Saadat Abad Blvd

City

Tehran

Province

Tehran

Postal code

1998734383

Phone

+98 21 2207 4087

Fax

+98 21 2207 4101

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

Seyed Ali Ziai

Street address

Velenjak St. , Shahid Chamran Highway

City

Tehran

Province

Tehran

Postal code

1985717434 , 1939547

Phone

+98 21 2243 9951

Fax

+98 21 2243 9784

Email

mpd@sbmu.ac.ir

Web page address

http://msp.sbmu.ac.ir/index.jsp?fkeyid=&siteid=73&pageid=7383

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
Mahnoosh Foroughi
Position
Professor
Latest degree
Specialist
Other areas of specialty/work
Cardiac surgery
Street address
District 2,Saadat Abad Blvd
City
Tehran
Province
Tehran
Postal code
1998734383
Phone
+98 21 2207 4087
Fax
+98 21 2207 4101
Email
Mahnoosh.foroughi@gmail.com
Web page address
https://modarres.sbmu.ac.ir

Person responsible for scientific inquiries

Contact
Name of organization / entity
Shahid Beheshti University of Medical Sciences
Full name of responsible person
Mahnoosh Foroughi
Position
Professor
Latest degree
Specialist
Other areas of specialty/work
Cardiac surgery
Street address
District 2,Saadat Abad Blvd
City
Tehran
Province
Tehran
Postal code
1998734383
Phone
+98 21 2207 4087
Fax
+98 21 2207 4101
Email
Mahnoosh.foroughi@gmail.com
Web page address
http://modarres.sbmu.ac.ir

Person responsible for updating data

Contact
Name of organization / entity
Shahid Beheshti University of Medical Sciences
Full name of responsible person
Mahnoosh Foroughi
Position
Professor
Latest degree
Specialist
Other areas of specialty/work
Cardiosurgery
Street address
SBUMS, Arabi Ave, Daneshjoo Blvd, Velenjak, Tehran, Iran.
City
Tehran
Province
Tehran
Postal code
1998734383
Phone
+98 21 2207 4087
Fax
+98 21 2207 4101
Email
Mahnoosh.foroughi@gmail.com
Web page address
Https://www.sbmu.ac.ir/

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
Yes - There is a plan to make this available
Informed Consent Form
Yes - There is a plan to make this available
Clinical Study Report
Yes - There is a plan to make this available
Analytic Code
Yes - There is a plan to make this available
Data Dictionary
Yes - There is a plan to make this available
Title and more details about the data/document
Result of study on vitamin D's affects on IL18,KIM1 urine

level and their association with CS-AKI. All documents will be available.

When the data will become available and for how long

About 6 months after publication ,data will become available.

To whom data/document is available

Documents will be available for academic institutions and people working in businesses.

Under which criteria data/document could be used

This document coud be useful for researchers interestend in related fields .

From where data/document is obtainable

Shahid beheshti university of medical sciences research affairs SBMU, Arabi Ave, Daneshjoo Blvd, Velenjak, Tehran, Iran. code:1985717443 Tel : 021-23871 Email: msp@sbmu.ac.ir Dr mahnoosh foroughi researcher. Email:mahnoosh.foroughi@gmail.com Pegah eslami researcher. Email:pegahslm@gmail.com

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

We will decide to accept or reject the application after a session in research center.

Comments