ISRCTN44896820 https://doi.org/10.1186/ISRCTN44896820

Can vitamin D reduce heart muscle damage after bypass surgery?

Submission date
17/11/2018

Recruitment status
No longer recruiting

Registration date
10/12/2018

Overall study status
Completed

Last Edited
07/09/2020

Condition category
Circulatory System

[_] Prospectively registered
[_] Protocol
[_] Statistical analysis plan
[X] Results
[_] Individual participant data

Plain English summary of protocol

Background and study aim
Heart diseases are among the most common cause of death worldwide. A large proportion of deaths are caused by heart attacks (myocardial infarction), where blood flow to the heart is reduced resulting in damage to the heart muscle. If the arteries supplying blood to the heart start to become blocked, coronary artery bypass graft (CABG) surgery to replace the blocked sections of artery can reduce angina (chest pain). However, CABG surgery has complications, including an increased risk of heart attack. Vitamin D deficiency is thought to be linked to poorer recovery from heart attack and CABG surgery. This study aims to investigate if vitamin D supplementation can reduce injury to the heart following CABG surgery.

Who can participate?
Adults with vitamin D deficiency undergoing CABG

What does the study involve?
Participants are randomly allocated to one of two groups. Those in the first group receive vitamin D at 3 doses per day for 3 days before surgery. The second group will receive a dummy pill (placebo). Both groups will have standard CABG surgery.

What are the possible benefits and risks of participating?
Those in the vitamin D group might benefit from its effects. Vitamin D has few side effects, especially when taken for only a few days.

Where is the study run from?
Shahid Modarres Hospital (Iran)

When is the study starting and how long is it expected to run for?
September 2017 to January 2019

Who is funding the study?
Deputy of Research of Shahid Beheshti School of Medicine

Who is the main contact?
Dr Erfan Tasdighi
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Contact information

Type(s)
Scientific

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Additional identifiers

EudraCT/CTIS number

IRAS number

ClinicalTrials.gov number

Secondary identifying numbers
1372

Study information

Scientific Title
Association between vitamin D administration and cardiac cell pathology in patients undergoing CABG surgery

Study objectives
Vitamin D administration in patients with vitamin D deficiency affect pathological features of cardiac muscle cells.

Ethics approval required
Old ethics approval format

Ethics approval(s)
Ethics committee of Shahid Beheshti Medical University, 04/11/2018, ref: IR.SBMU.RETECH.REC.1397.616

Study design
Randomized controlled trial

Primary study design
Interventional

Secondary study design
Randomised controlled trial

Study setting(s)
Hospital

Study type(s)
Treatment

Participant information sheet
Not available in web format, please use the contact details below to request a participant information sheet

Health condition(s) or problem(s) studied
Prevention of cardiomyopathy following CABG surgery

Interventions
Participants undergoing coronary artery bypass graft (CABG) surgery are randomly allocated to group A (intervention), who receive 3 doses of vitamin D (50000 U) a day for 3 days before surgery or group B (control), who will receive placebo.

Intervention Type
Supplement

Primary outcome measure
1. Caspase 2 enzyme level measured by IHC (immunohistochemistry) of right atrial auricle biopsy during and after surgery
2. Caspase 3 enzyme level measured by IHC of right atrial auricle biopsy during and after surgery
3. Caspase 7 enzyme level measured by IHC of right atrial auricle biopsy during and after surgery
4. Serum IL-10 level measured by ELISA before the intervention (3 days before surgery), just before the surgery, just after surgery and one day after surgery
5. Serum insulin-like growth factor level measured by standard laboratory test before the intervention (3 days before surgery), just before surgery, just after the surgery and one day after surgery

Secondary outcome measures
1. Blood loss during surgery measured by suction device
2. Blood units usage assessed by counting the number of packed cells that have been used during the surgery
3. Ventilation time measured by ventilator machine during and after surgery
4. Kidney damage assessed by blood creatinine level before the intervention (3 days before surgery), just after the surgery and one day after surgery

Overall study start date

10/09/2017

Completion date
21/01/2019

Eligibility

Key inclusion criteria
1. Candidate for first-time elective CABG surgery for coronary artery disease (CAD)
2. Coronary artery surgery only (i.e. no valvular surgery)
3. Cardiopulmonary pump used during surgery
4. Vitamin D level below 30 ng/ml

Participant type(s)
Patient

Age group
Adult

Sex
Both

Target number of participants
66

Total final enrolment
70

Key exclusion criteria
1. Renal failure or creatinine level >1.5 mg/dl
2. Previous use of vitamin D supplement

Date of first enrolment
20/10/2018

Date of final enrolment
23/12/2018

Locations

Countries of recruitment
Iran

Study participating centre
Shahid Modarres Hospital
Saadat Abad

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Sponsor information

Organisation
Shahid Beheshti University of Medical Sciences

Sponsor details
Deputy of Research of School of Medicine
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Sponsor type
University/education

ROR
https://ror.org/034m2b326

Funder(s)

Funder type
Other

Funder Name
investigator initiated and funded

Results and Publications

Publication and dissemination plan
Planned publication in a high-impact peer-reviewed journal.

Intention to publish date
31/03/2020

Individual participant data (IPD) sharing plan

All data sets including demographic, preoperative and postoperative ones will be available after results publication. All data sets can be shared, if the recipients mention this study in their project. Any kind of analysis can be performed on these data sets. There was no need for patient consent, because all data sets are in codes and have no patient names in them. Anyone who needs the data sets can send a request form to Dr Mahnoosh Foroughi (mahnoosh.foroughi@gmail.com).

IPD sharing plan summary

Stored in repository

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
Results article	results	01/07/2020	07/09/2020	Yes	No