Clinical Trial Protocol
Iranian Registry of Clinical Trials

22 Nov 2026

comparison of dexmedetomidin and placebo on postoperative atrial fibrillation control in patients undergoing coronary artery bypass graft surgery

Protocol summary

Summary

This study will be done as a random double blind clinical trial .The aim of this study is to investigate the effect of dexmedetomidine on postoperative atrial fibrillation in patients under coronary artery bypass graft surgery. In this study, 110 patients undergoing elective coronary artery bypass surgery will be randomly divided in two groups of dexmedetomidine and placebo. Randomization will be performed through block randomization method. Inclusion criteria: elective CABG surgery; 35 to 65 year old patients; 3 or more coronary artery stenosis. Exclusion criteria: pre-operative diagnosed bradycardia. Intervention group will receive an infusion of dexmedetomidine after induction, as much as 0.3-0.5 µgr/kg per hour for 24 hours. Control group will receive infusion of normal salin after induction, as much as 0.3-0.5 µgr/kg per hour for 24 hours. Anesthesia and surgery method will be the same according to the standard protocol in both groups. All surgeries will be performed by one surgeon. The incidence of postoperative atrial fibrillation will be recorded by bedside monitoring and 12 lead electrocardiograms. Outcomes of interest: First time of receiving bolus morphine, total dose of morphine received during first 48 hours after surgery.

General information

Acronym

IRCT registration information

IRCT registration number: **IRCT2017021914359N4**
Registration date: **2017-03-20, 1395/12/30**
Registration timing: **registered_while_recruiting**

Last update:
Update count: **0**

Registration date

2017-03-20, 1395/12/30

Registrant information

Name
Vally Imantalab
Name of organization / entity
Guilan University of Medical Sciences
Country
Iran (Islamic Republic of)
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Recruitment status

Recruitment complete

Funding source

Vice chancellor for research of Guilan University of Medical Sciences

Expected recruitment start date

2017-03-05, 1395/12/15

Expected recruitment end date

2017-06-05, 1396/03/15

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

comparison of dexmedetomidin and placebo on postoperative atrial fibrillation control in patients undergoing coronary artery bypass graft surgery

Public title

effect of dexmedetomidin on post CABG atrial fibrillation

Purpose

Prevention

Inclusion/Exclusion criteria
Inclusion criteria: elective CABG surgery; 35 to 65 year old patients; 3 or more coronary artery stenosis; EF>45%; normal sinus rhythm; normal liver and kidney function. Exclusion criteria: pre-operative diagnosed bradycardia; HR<50; pregnancy; thyroid dysfunction; uncontrolled diabetes; history of corticosteroids use; addiction.

Age
From **35 years** old to **65 years** old

Gender
Both

Phase
2-3

Groups that have been masked
No information

Sample size
Target sample size: **110**

Randomization (investigator's opinion)
Randomized

Randomization description

Blinding (investigator's opinion)
Double blinded

Blinding description

Placebo
Used

Assignment
Parallel

Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee
Ethics committee of Guilan University of Medical Sciences

Street address
Shahid Beheshti highway

City
Rasht

Postal code

Approval date
2016-10-30, 1395/08/09

Ethics committee reference number
IR.GUMS.REC.1395.312

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
Morphin requirement

Timepoint
within 48 hours after ICU admission

Method of measurement
Visual analogue score

2

Description
onset of atrial fibrillation

Timepoint
Within 24 hours of ICU admission

Method of measurement
ECG 12 lead whenever seen arrhythmia in monitoring and 24 hours monitoring

Secondary outcomes

empty

Intervention groups

1

Description
Intervention group: An infusion of dexmedetomidine after induction, as much as 0.3-0.5 µgr/kg per hour for 24 hours

Category
Treatment - Drugs

2

Description
Control group: infusion of normal salin after induction, as much as 0.3-0.5 µgr/kg per hour for 24 hours.

Category
Treatment - Drugs

Recruitment centers

1

Recruitment center

Name of recruitment center
Heshmat hospital

Full name of responsible person
Vali Imantalab

Street address
Heshmat square

City
Rasht

Sponsors / Funding sources

1

Sponsor
Name of organization / entity
Vice Chancellor for research of Guilan university of medical sciences
Full name of responsible person
Shadman naemati
Street address
Shahid Beheshti
City
Rasht
Grant name
Grant code / Reference number
Is the source of funding the same sponsor organization/entity?
Yes
Title of funding source
Vice Chancellor for research of Guilan university of medical sciences
Proportion provided by this source
100
Public or private sector
empty
Domestic or foreign origin
empty
Category of foreign source of funding
empty
Country of origin
Type of organization providing the funding
empty

Person responsible for general inquiries

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Person responsible for updating data

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Sharing plan

Deidentified Individual Participant Data Set (IPD)
empty
Study Protocol
empty
Statistical Analysis Plan
empty
Informed Consent Form
empty
Clinical Study Report
empty
Analytic Code
empty
Data Dictionary
empty