

Clinical Trial Protocol

Iranian Registry of Clinical Trials

11 Sep 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 µg/kg per hour for 24 hours. Control group will receive infusion of normal saline after induction, as much as 0.3-0.5 µg/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)

Phone

+98 13 1666 9064

Email address

vimantalab@gums.ac.ir

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 saline 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

Contact**Name of organization / entity**

Heshmat hospital

Full name of responsible person

Dr Vali Imantalab

Position

associate professor

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

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Person responsible for scientific inquiries

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Heshmat square

Full name of responsible person

Dr Vali Imantalab

Position

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Person responsible for updating data

Contact**Name of organization / entity**

Anesthesiology Research Center

Full name of responsible person

Mahsa Riazi

Position

Research Expert / MA in administration

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

Vellayat Hospital

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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