Clinical Trial Protocol
Iranian Registry of Clinical Trials

22 Nov 2026

Investigating the protective effect of dexmedetomidine on myocardial injury in on-pump coronary artery bypass grafting (CABG) surgery

Protocol summary

Summary

The current study as a random double blind clinical trial will be done. The aim of this study is to investigate the protective effect of dexmedetomidine on myocardial injury in on-pump coronary artery bypass grafting (CABG) surgery.110 patients undergoing elective coronary artery bypass surgery will be randomly divided into two groups of dexmedetomidine and control.Inclusion criteria: Isolated and elective CABG surgery; Age 35 to 65 years old; 3 or 4 coronary artery stenosis; Exclusion criteria: Patients with bradycardy based on preoperative diagnosis.The dexmedetomidine group will receive an infusion of dexmedetomidine (0.3 - 0.5 µ/kg/h) for 24 hours. In Contrl group: An infusion of normal salin (0.3 - 0.5 µ/kg/h) after induction for 24 hours.Anesthesia and surgery will be carried out according to the standard protocol. One surgeon will perform all surgeries.Troponin I, CK-MB and Serum Cortisol level will be measured at 5 point times. Before anesthesia (T0), 6 hrs post-surgery (T1), 12 hrs post-surgery (T2), 24 hrs post-surgery (T3), 48 hrs post-surgery (T4).

General information

Acronym

IRCT registration information

IRCT registration number: **IRCT2016071113456N6**
Registration date: **2016-08-02, 1395/05/12**
Registration timing: **prospective**

Last update:
Update count: **0**

Registration date

2016-08-02, 1395/05/12

Registrant information

Name

Abbas Sedighinejad

Name of organization / entity

Guilan University of Medical Sciences

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Recruitment status

Recruitment complete

Funding source

Vice chancellor for research of Guilan University of Medical Sciences

Expected recruitment start date

2016-08-05, 1395/05/15

Expected recruitment end date

2016-12-05, 1395/09/15

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Investigating the protective effect of dexmedetomidine on myocardial injury in on-pump coronary artery bypass grafting (CABG) surgery

Public title

Cardio protective effect of dexmedetomidine in CABG

Purpose

Prevention

Inclusion/Exclusion criteria

Inclusion criteria: Isolated and elective CABG surgery; Age 35 to 65 years old; 3 or 4 coronary artery stenosis; EF>45%;Normal sinus rhythm and normal heart rate; myocardial enzymes troponin and CK-MB levels before surgery in normal range; Exclusion criteria:Heart

Rate<50; SBP<90 mmHg;Thyroid dysfunction uncontrolled diabetes; History of corticosteroid therapy; 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
Randomized in blocks quaternary

Secondary Ids

empty

Ethics committees

1

Ethics committee

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

Street address
Shahid Beheshti Freeway

City
Rasht

Postal code
4193833697

Approval date
2016-05-10, 1395/02/21

Ethics committee reference number
IR.GUMS.REC.1395.46

Health conditions studied

1

Description of health condition studied
myocardial injury

ICD-10 code
I97.1

ICD-10 code description
Other functional disturbances following cardiac surgery

Primary outcomes

1

Description
Levels of CK-MB

Timepoint
Before anesthesia(T0); 6 hr post surgery(T1); 12 hrs post surgery (T2) ; 24 hrs post surgery (T3) ;48 hrs post surgery (T4)

Method of measurement
Immunoassay

2

Description
Serum Cortisol level

Timepoint
Before anesthesia(T0); 6 hr post surgery(T1); 12 hrs post surgery (T2) ; 24 hrs post surgery (T3) ;48 hrs post surgery (T4)

Method of measurement
Immunoassay

Secondary outcomes

1

Description
Serum levels of Troponin I

Timepoint
Before anesthesia(T0); 6 hr post surgery(T1); 12 hrs post surgery (T2) ; 24 hrs post surgery (T3) ;48 hrs post surgery (T4)

Method of measurement
immunoassay

Intervention groups

1

Description
Intervention group: An infusion of dexmedetomidine (0.3 - 0.5 µ/kg/h) after induction for 24 hours

Category
Treatment - Drugs

2

Description
Contrl group: An infusion of normal salin((0.3 - 0.5 µ/kg/h) after induction for 24 hours

Category
Treatment - Drugs

Recruitment centers

1

Recruitment center

Name of recruitment center
Heshmat Hospital

Full name of responsible person
Abbas Sedighinejad
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Hashmat Square
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Sponsors / Funding sources

1

Sponsor
Name of organization / entity
Vice chancellor for research of Guilan University of Medical Sciences
Full name of responsible person
Dr. Tabari
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Shahid Beheshti Freeway
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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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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