

Clinical Trial Protocol

Iranian Registry of Clinical Trials

11 Sep 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 bradycardia based on preoperative diagnosis. The dexmedetomidine group will receive an infusion of dexmedetomidine (0.3 - 0.5 µ/kg/h) for 24 hours. In Control group: An infusion of normal saline (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

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

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

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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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Person responsible for scientific inquiries**Contact****Name of organization / entity**

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Full name of responsible person

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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**Contact****Name of organization / entity**

Guilan University of Medical Sciences

Full name of responsible person

Abbas Sedighinejad

Position

Anesthesiologist/Associated Proffesor

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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