

# Clinical Trial Protocol

## Iranian Registry of Clinical Trials

27 Jul 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)

##### Phone

+98 911 132 5712

##### Email address

a\_sedighinejad@gums.ac.ir

##### 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

**Street address**

Hashmat Square

**City**

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arcguilan1392@gmail.com

**Web page address**

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

Guilan University of Medical Science

**Full name of responsible person**

Abbas Sedighinejad

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Anesthesiologist/Associated Proffessor

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

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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

**Street address**

Shahid Beheshti Freeway

**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**

Guilan University of Medical Sciences

**Full name of responsible person**

Abbas Sedighinejad

**Position**

Anesthesiologist/Associated Proffesor

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

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**Email****Person responsible for updating data****Contact****Name of organization / entity**

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**Full name of responsible person**

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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*