

Clinical Trial Protocol

Iranian Registry of Clinical Trials

04 Jul 2026

Comparison and evaluation of cognitive impairment and cognitive function changes in patients undergoing coronary artery bypass graft surgery after premedication with doxedmodyntidine and midazolam

Protocol summary

Study aim

Determination of cognitive impairment and cognitive function changes in patients undergoing coronary artery bypass graft surgery using post-beating-on post-treatment with doxedetomidine and midazolam

Design

42 patients who undergo general anesthesia and the coronary artery bypass graft surgery with age of 40-45 are entered in this study . On the day of operation, patients are randomly divided into two groups that case group receive Dexmedetomidine and control group receive Midazolam. This study is double-blind that researcher and patients are unaware.

Settings and conduct

This project was conducted at Mashhad University of Medical Sciences. This study is double-blind that researcher and patients are unaware.

Participants/Inclusion and exclusion criteria

Patients undergoing beating-on-pump coronary artery bypass surgery under general anesthesia in hospitals affiliated to Mashhad University of Medical Sciences

Intervention groups

Intervention group: Premedication with midazolam at a dose of 0.5-0.1 mg / kg and fentanyl at a dose of 1.0-5 µg / g for propofol for induction of anesthesia and muscle relaxant to facilitate intubation. Control group: Dexamethadone dosage of 0.5 to 0.1 mg / kg and fentanyl with g / kg 10-5-polypropofol for induction of anesthesia and muscle relaxant are used to facilitate intubation.

Main outcome variables

Cognitive status before and after surgery

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20170429033680N7**

Registration date: **2018-02-28, 1396/12/09**

Registration timing: **retrospective**

Last update: **2018-02-28, 1396/12/09**

Update count: **0**

Registration date

2018-02-28, 1396/12/09

Registrant information

Name

Farideh Golhasani

Name of organization / entity

Mashhad University of Medical Sciences

Country

Iran (Islamic Republic of)

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golhasanif1@mums.ac.ir

Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2016-11-02, 1395/08/12

Expected recruitment end date

2018-02-27, 1396/12/08

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Comparison and evaluation of cognitive impairment and

cognitive function changes in patients undergoing coronary artery bypass graft surgery after premedication with doxedmodytidine and midazolam

Public title

Comparison and evaluation of cognitive impairment and cognitive function changes in patients undergoing coronary artery bypass graft surgery after premedication with doxedmodytidine and midazolam

Purpose

Prevention

Inclusion/Exclusion criteria

Inclusion criteria:

Patient satisfaction On-pump surgery Age 40 to 65 years old

Exclusion criteria:

A cardiovascular disease and prolonged CPR DVT history in the last 6 months A history of advanced kidney or lung disease Duration of surgery for more than 5 hours

Age

From **40 years** old to **65 years** old

Gender

Both

Phase

3

Groups that have been masked

- Participant
- Investigator

Sample size

Target sample size: **42**

Randomization (investigator's opinion)

Randomized

Randomization description

simple randomization: Randomization is done using enveloped packets

Blinding (investigator's opinion)

Double blinded

Blinding description

The participants and the investigator were not aware of the type of medication

Placebo

Not used

Assignment

Parallel

Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee

Ethics committee of Mashhad University of Medical sciences

Street address

Mashhad University of Medical Sciences; International Offic Administration Center(Qoreishi Building) ;

Daneshgah St

City

Mashhad

Province

Razavi Khorasan

Postal code

9138813944

Approval date

2016-11-02, 1395/08/12

Ethics committee reference number

IR.MUMS.sm.REC.1394.553

Health conditions studied

1

Description of health condition studied

coronary arteries

ICD-10 code

R41.8

ICD-10 code description

Other symptoms and signs involving cognitive functions and awareness

Primary outcomes

1

Description

Cognitive function of patients

Timepoint

before and after surgery

Method of measurement

Scale

Secondary outcomes

1

Description

Blood pressure

Timepoint

after intervation

Method of measurement

Barometer

Intervention groups

1

Description

Intervention group: premedication with midazolam 0.5 and 1 mg / kg

Category

Treatment - Drugs

2

Description

Control group: Dexmedetomidine at a dose of 1 microgram per kilogram

Category

Treatment - Drugs

Recruitment centers**1****Recruitment center****Name of recruitment center**

Imam Reza Hospital

Full name of responsible person

Mahsa Rajaei

Street addressDepartment of Anesthesiology, Imam Reza (AS)
Hospital, Taghiabad Square**City**

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Sponsors / Funding sources**1****Sponsor****Name of organization / entity**

Mashhad University of Medical Sciences

Full name of responsible person

Marjan Ardakanian

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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

Mashhad University of Medical Sciences

Proportion provided by this source

100

Public or private sector

Public

Domestic or foreign origin

Domestic

Category of foreign source of funding

empty

Country of origin**Type of organization providing the funding**

Academic

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

Mashhad University of Medical Sciences

Full name of responsible person

Mahsa Rajaei

Position

resident

Latest degree

Medical doctor

Other areas of specialty/work

Anesthesiology

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Person responsible for updating data

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Sharing plan

Deidentified Individual Participant Data Set (IPD)

Yes - There is a plan to make this available

Study Protocol

Yes - There is a plan to make this available

Statistical Analysis Plan

Yes - There is a plan to make this available

Informed Consent Form

Yes - There is a plan to make this available

Clinical Study Report

Yes - There is a plan to make this available

Analytic Code

Yes - There is a plan to make this available

Data Dictionary

Undecided - It is not yet known if there will be a plan to
make this available

Title and more details about the data/document

Article

When the data will become available and for how long

1397

To whom data/document is available

web site

Under which criteria data/document could be used

Researchers

From where data/document is obtainable

sent an email

What processes are involved for a request to access data/document

one week after received email

Comments