Clinical Trial Protocol
Iranian Registry of Clinical Trials

17 Sep 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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+98 51 3802 2631

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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 doxedmodyntidine 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 doxedmodyntidine 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 address
Department of Anesthesiology, Imam Reza (AS) Hospital, Taghiabad Square
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Sponsors / Funding sources

1

Sponsor
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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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Anesthesiology

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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