Clinical Trial Protocol
Iranian Registry of Clinical Trials

22 Nov 2026

The effect of dexmedetomidine on hemodynamic changes in patients undergoing coronary artery bypass graft

Protocol summary

Study aim
The effect of dexmedetomidine on hemodynamic changes in patients undergoing coronary artery bypass graft (CABG)

Design
Phase-II randomized controlled trial, with parallel groups; without blinding; on 72 patients, randomization with sealed envelopes

Settings and conduct
This randomized controlled trial will include 72 candidates of elective coronary bypass graft (CABG) with cardiopulmonary bypass (CPB) in Payambar Azam Hospital, Bandar Abbas. Patients will randomly be allocated to two groups. In the dexmedetomidine group, 0.5 mcg/kg of the drug will be injected intravenously withing 10 min. The control group will not receive dexmedetomidine. Hemodynamic parameters, including systolic and diastolic blood pressure, mean arterial pressure, heart rate, systemic vascular resistance, central venous pressure, and cardiac output will be measured and recorded at different time points in both groups. Also, pump time and aortic clamp time will be recorded for all patients. Inotrope requirement and its administered dose will also be noted for all patients.

Participants/Inclusion and exclusion criteria
Inclusion criteria: Age 30-80 year; American Society of Anesthesiologists (ASA) class II, III, and IV; Candidates of elective coronary artery bypass graft (CABG) with cardiopulmonary bypass (CPB). Exclusion criteria: Emergency surgery; Ejection fraction <30%; Concurrent valvular surgery; Any complication during surgery and pacemaker requirement.

Intervention groups
Intervention group: A 0.5 mcg/kg dose of dexmedetomidine will be injected intravenously withing 10 min before anesthesia induction. Control group: Anesthesia induction without dexmedetomidine injection.

Main outcome variables
Blood pressure

General information

Reason for update

Acronym

IRCT registration information
IRCT registration number: **IRCT20220316054311N1**
Registration date: **2022-03-24, 1401/01/04**
Registration timing: **registered_while_recruiting**

Last update: **2022-03-24, 1401/01/04**
Update count: **0**

Registration date
2022-03-24, 1401/01/04

Registrant information

Name
Seyed Mohammad Abtahi

Name of organization / entity

Country
Iran (Islamic Republic of)

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+98 76 3334 5009

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Recruitment status
Recruitment complete

Funding source

Expected recruitment start date
2021-12-22, 1400/10/01

Expected recruitment end date
2022-04-04, 1401/01/15

Actual recruitment start date
empty

Actual recruitment end date
empty

Trial completion date
empty

Scientific title

The effect of dexmedetomidine on hemodynamic changes in patients undergoing coronary artery bypass graft

Public title
The effect of dexmedetomidine on hemodynamic changes in patients undergoing coronary artery bypass graft
Purpose
Treatment
Inclusion/Exclusion criteria
Inclusion criteria:
Age 30-80 years American Society of Anesthesiologists (ASA) class II, III, and IV Candidates of elective coronary artery bypass graft (CABG) with cardiopulmonary bypass (CPB)
Exclusion criteria:
Emergency surgery Ejection fraction <30% Concurrent valvular sugery Any complication during surgery and pacemaker requirement
Age
From **30 years** old to **80 years** old
Gender
Both

Phase
3
Groups that have been masked
No information
Sample size
Target sample size: **72**
Randomization (investigator's opinion)
Randomized
Randomization description
Simple randomization with individuals as units of randomization along with allocation concealment: 72 unclear envelopes and 72 cards with the names of the groups (A, B) will be prepared (36 cards for each group). The cards will be put into the envelopes and the envelopes will be sealed and provided to the investigator. Upon entrance of each patient to the study, the envelopes will be shuffled and one will randomly be selected. The patient will be allocated to group A or B based on the card inside the selected envelope.
Blinding (investigator's opinion)
Not blinded
Blinding description
Placebo
Not used
Assignment
Parallel
Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee
Name of ethics committee
Ethics Committee of Hormozgan University of Medical Sciences
Street address
Imam Hossein Blvd., across from Kargaran Sports Complex, Faculty of Medicine
City
Bandar Abbas
Province
Hormozgan
Postal code
7916613885
Approval date
2021-07-05, 1400/04/14
Ethics committee reference number
IR.HUMS.REC.1400.132

Health conditions studied

1

Description of health condition studied
coronary artery bypass graft
ICD-10 code
I25.709
ICD-10 code description
Atherosclerosis of coronary artery bypass graft(s), unspecified, with unspecified angina pectoris

Primary outcomes

1

Description
Blood pressure
Timepoint
Baseline, before sternotomy, immediately after sternotomy and then at 10, 20, 30, 40, 50, and 60 min, before CPB, before cross clamp removal, before weaning, after weaning, before sternal closure, after sternal closure, at 1, 2, 3, 4, 5, and 6 hour in the intensive care unit
Method of measurement
Monitoring device

Secondary outcomes

1

Description
Mean arterial pressure
Timepoint
Baseline, before sternotomy, immediately after sternotomy and then at 10, 20, 30, 40, 50, and 60 min, before CPB, before cross clamp removal, before weaning, after weaning, before sternal closure, after sternal closure, at 1, 2, 3, 4, 5, and 6 hour in the intensive care unit
Method of measurement
Monitoring device

2

Description
Systemic vascular resistance
Timepoint
Baseline, before sternotomy, immediately after sternotomy and then at 10, 20, 30, 40, 50, and 60 min, before CPB, before cross clamp removal, before weaning, after weaning, before sternal closure, after sternal closure, at 1, 2, 3, 4, 5, and 6 hour in the intensive care unit
Method of measurement
Monitoring device

3

Description
Cardiac output
Timepoint
Baseline, before sternotomy, immediately after sternotomy and then at 10, 20, 30, 40, 50, and 60 min, before CPB, before cross clamp removal, before weaning, after weaning, before sternal closure, after sternal closure, at 1, 2, 3, 4, 5, and 6 hour in the intensive care unit
Method of measurement
Monitoring device

4

Description
Heart rate
Timepoint
Baseline, before sternotomy, immediately after sternotomy and then at 10, 20, 30, 40, 50, and 60 min, before CPB, before cross clamp removal, before weaning, after weaning, before sternal closure, after sternal closure, at 1, 2, 3, 4, 5, and 6 hour in the intensive care unit
Method of measurement
Monitoring device

5

Description
Central venous pressure
Timepoint
Baseline, before sternotomy, immediately after sternotomy and then at 10, 20, 30, 40, 50, and 60 min, before CPB, before cross clamp removal, before weaning, after weaning, before sternal closure, after sternal closure, at 1, 2, 3, 4, 5, and 6 hour in the intensive care unit
Method of measurement
Monitoring device

6

Description
Cross clamp time
Timepoint
During surgery
Method of measurement
Clinical assessment

7

Description
Pump time
Timepoint
During surgery
Method of measurement
Clinical assessment

8

Description
Inotrope requirement
Timepoint
During surgery
Method of measurement
Clinical assessment

Intervention groups

1

Description
Intervention group: In the dexmedetomidine group, one dose of the drug at 0.5 mcg/kg will be injected intravenously within 10 min.
Category
Treatment - Drugs

2

Description
Control group: They will receive no dexmedetomidine.
Category
Other

Recruitment centers

1

Recruitment center
Name of recruitment center
Payambar Azam Hospital
Full name of responsible person
Seyed Mohammad Abtahi
Street address
Jomhouri Eslami Blvd., Payambar Azam Hospital
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Sponsors / Funding sources

1

Sponsor
Name of organization / entity
Vice-Chancellery for Research Hormozgan University of Medical Sciences
Full name of responsible person
Teamur Aghamolaei
Street address
Imam Hossein Blvd., across from Kargaran Sports Complex
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teaghamolaei@gmail.com
Web page address
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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-Chancellery for Research Hormozgan 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
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Full name of responsible person
Seyed Mohammad Abtahi
Position
Resident
Latest degree
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Other areas of specialty/work
Anesthesiology
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Sharing plan

Deidentified Individual Participant Data Set (IPD)
No - There is not a plan to make this available
Justification/reason for indecision/not sharing IPD
There is no further information.
Study Protocol
No - There is not a plan to make this available
Statistical Analysis Plan
No - There is not a plan to make this available
Informed Consent Form
No - There is not a plan to make this available
Clinical Study Report
No - There is not a plan to make this available
Analytic Code
No - There is not a plan to make this available
Data Dictionary
No - There is not a plan to make this available