

Clinical Trial Protocol

Iranian Registry of Clinical Trials

11 Sep 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)

Phone

+98 76 3334 5009

Email address

abtahi_mohamad@yahoo.com

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		Ethics Committee of Hormozgan University of Medical Sciences	
Public title	The effect of dexmedetomidine on hemodynamic changes in patients undergoing coronary artery bypass graft	Street address	Imam Hossein Blvd., across from Kargaran Sports Complex, Faculty of Medicine
Purpose	Treatment	City	Bandar Abbas
Inclusion/Exclusion criteria		Province	Hormozgan
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)	Postal code	7916613885
Exclusion criteria:	Emergency surgery Ejection fraction <30% Concurrent valvular surgery Any complication during surgery and pacemaker requirement	Approval date	2021-07-05, 1400/04/14
Age	From 30 years old to 80 years old	Ethics committee reference number	IR.HUMS.REC.1400.132
Gender	Both	Health conditions studied	
Phase	3	1	
Groups that have been masked	No information	Description of health condition studied	
Sample size	Target sample size: 72	coronary artery bypass graft	
Randomization (investigator's opinion)	Randomized	ICD-10 code	
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.	I25.709	
Blinding (investigator's opinion)	Not blinded	ICD-10 code description	
Blinding description		Atherosclerosis of coronary artery bypass graft(s), unspecified, with unspecified angina pectoris	
Placebo	Not used	Primary outcomes	
Assignment	Parallel	1	
Other design features		Description	
Secondary Ids	empty	Blood pressure	
Ethics committees		Timepoint	
1		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	
Ethics committee		Method of measurement	
Name of ethics committee		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

Jomhour Eslami Blvd., Payambar Azam Hospital

City

Bandar Abbas

Province

Hormozgan

Postal code

9791991551

Phone

+98 76 3334 7000

Fax

+98 76 3334 5003

Email

shmh@hums.ac.ir

Web page address

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 Kargar Sports Complex

City

Bandar Abbas

Province

Hormozgan

Postal code

7919693116

Phone

+98 76 3371 0393

Email

teaghamolaei@gmail.com

Web page address

<https://resv.hums.ac.ir/>

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**

Bandare-abbas University of Medical Sciences

Full name of responsible person

Seyed Mohammad Abtahi

Position

Resident

Latest degree

Medical doctor

Other areas of specialty/work

Anesthesiology

Street address

Jomhouri Eslami Blvd., Payambar Azam Hospital

City

Bandar Abbas

Province

Hormozgan

Postal code

9791991551

Phone

+98 76 3334 5009

Email

abtahi_mohamad@yahoo.com

Person responsible for scientific inquiries

Contact**Name of organization / entity**

Bandare-abbas University of Medical Sciences

Full name of responsible person

Seyed Mohammad Abtahi

Position

Resident

Latest degree

Medical doctor

Other areas of specialty/work

Anesthesiology

Street address

Jomhouri Eslami Blvd., Payambar Azam Hospital

City

Bandar Abbas

Province

Hormozgan

Postal code

9791991551

Phone

+98 76 3334 5009

Email

abtahi_mohamad@yahoo.com

Person responsible for updating data

Contact**Name of organization / entity**

Bandare-abbas University of Medical Sciences

Full name of responsible person

Seyed Mohammad Abtahi

Position

Resident

Latest degree

Medical doctor

Other areas of specialty/work

Anesthesiology

Street address

Jomhouri Eslami Blvd., Payambar Azam Hospital

City

Bandar Abbas

Province

Hormozgan

Postal code

9791991551

Phone

+98 76 3334 5009

Email

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