Clinical Trial Protocol
Iranian Registry of Clinical Trials

22 Nov 2026

The effect of aortic root infusion of Dexmedetomidine before de-clamping of the aorta on myocardial protection in patients undergoing Mitral valve replacement/ repair

Protocol summary

Study aim
Evaluating the effect of dexmedetomidine infusion in the aortic root before aortic cross clamp removal on myocardial protection in patients undergoing mitral valve replacement / repair.

Design
A controlled clinical trial with superiority, with parallel groups, three-way blind, randomized block method, phase 3 on 58 patients, www.randomization.com is used for randomization.

Settings and conduct
Patients scheduled for mitral valve repair or replacement were randomly assigned to either dexmedetomedine or placebo group. Before entering the operating room, blood samples will be sent to all patients to test for troponin I and creatinine kinase-MB. Within 6 hours of entering the Intensive Care Unit, 12 hours later and 24 hours after entering the Intensive Care Unit, the sample will be repeated and the results will be recorded. Also, patients' urinary output is recorded in the first 6 hours, the first 12 hours and 24 hours after surgery.

Participants/Inclusion and exclusion criteria
The study population included patients seeking mitral valve repair or replacement with a ejection fraction above 40%, and no history of supraventricular dysrhythmias, no history of cardiac surgery, nephropathy following the use of contrast agents (CIN), respiratory failure, Stroke and TIA, And coagulopathy.

Intervention groups
At the end of the surgical procedure, before removing the aortic clamp, at the root of the aorta of patients, using a cardioplegia needle, a solution of dexmedetomidine with a concentration of 4 µg / ml, at a rate of 1 µg / kg / h, for 10 minutes, Is infused. At the end of the surgical procedure, before removing the aortic clamp, in the aortic root of patients, using a cardioplegia needle, 0.9% sodium chloride solution at a rate of 1 ml / kg / hour for 10 minutes infusion will be.

Main outcome variables
Troponin and CPK-MB changes

General information

Reason for update

Acronym

IRCT registration information
IRCT registration number: **IRCT20210710051837N1**
Registration date: **2021-10-18, 1400/07/26**
Registration timing: **registered_while_recruiting**

Last update: **2021-10-18, 1400/07/26**
Update count: **0**

Registration date
2021-10-18, 1400/07/26

Registrant information

Name
Fateme Hajipour aghmashhadi

Name of organization / entity

Country
Iran (Islamic Republic of)

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+98 11 3328 0646

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hajipouraf981@mums.ac.ir

Recruitment status
Recruitment complete

Funding source

Expected recruitment start date
2021-07-23, 1400/05/01

Expected recruitment end date
2021-11-16, 1400/08/25

Actual recruitment start date
empty

Actual recruitment end date
empty
Trial completion date
empty

Scientific title
The effect of aortic root infusion of Dexmedetomidine before de-clamping of the aorta on myocardial protection in patients undergoing Mitral valve replacement/ repair

Public title
The effect of Dexmedetomidine on myocardial protection in patients undergoing Mitral valve replacement/ repair
Purpose
Prevention
Inclusion/Exclusion criteria
Inclusion criteria:
Candidate patients for mitral valve repair or replacement with ejection fraction above 40%
Exclusion criteria:
Supraventricularor ventricular dysrhythmias History of heart surgery Nephropathy following the use of contrast agent (CIN) Hypercapnic or hypoxic Respiratory failure Patients with a history of Stroke and TIA Patients with a history of Coagulopathy Use of an intra-aortic balloon pump (IABP) before and during surgery Use of vasopressor before surgery Patient dissatisfaction to participate in the study The presence of any pathological disorder leads to the release of inflammatory cytokines Cardiopulmonary arrest before, during and after surgery
Age
From **18 years** old
Gender
Both

Phase
3
Groups that have been masked

- Participant
- Outcome assessor
- Data analyser

Sample size
Target sample size: **56**
Randomization (investigator's opinion)
Randomized
Randomization description
The randomized block method and using the site www.randomization.com Block: This method is used to prevent significant imbalances in the number of participants assigned to each group. Block randomization ensures that no significant imbalance is established between groups at any time during randomization, and at certain points the number of participants in each group is equal. For this method, the volume of each block must first be determined (Example of a quadruple block). Then write a list of blocks and assign numbers to them (AABB (1) - ABAB (2) -ABBA (3) -BBAA (4) - BABA (5) - BAAB (6)) Then select random numbers between one and 6 (Eg 1 4 5 and ...) and finally specify the treatment allocation list based on previous random numbers (AB AABB-BBAA-BABA-).} Allocation Concealment Allocation Method: The lottery is done using the envelope in the package.
Blinding (investigator's opinion)
Triple blinded
Blinding description
Subjects, Evaluators and Analysts will be unaware of the solutions administered to the aortic roots of the intervention and control groups. As we will define the syringe containing the solutions with the labels A and B, and the Subjects, Evaluators and Analysts are not aware of the contents of the syringe.
Placebo
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
East door of the University Campus, Azadi Square, Mashhad Town
City
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Province
Razavi Khorasan
Postal code
۹۱۷۷۹۴۸۵۴۴
Approval date
2021-07-12, 1400/04/21
Ethics committee reference number
IR.MUMS.MEDICAL.REC.1400.186

Health conditions studied

1

Description of health condition studied
The effect of aortic root infusion of Dexmedetomidine before de-clamping of the aorta on myocardial protection in patients undergoing Mitral valve replacement/ repair
ICD-10 code
105.9
ICD-10 code description
Mitral (valve) disorder (chronic) NOS

Primary outcomes

1

Description
Troponin I Assay
Timepoint

Before entering the operating room, In the first hour, 6 hours later, 12 hours later and 24 hours after entering the Intensive Care Unit

Method of measurement

Blood Sample

2

Description

Creatinine kinease _MB Assay

Timepoint

Before entering the operating room, In the first hour, 6 hours later, 12 hours later and 24 hours after entering the Intensive Care Unit

Method of measurement

Blood Sample

3

Description

The rate of urinary outputs

Timepoint

The first 6 hours, the first 12 hours and 24 hours after the operation

Method of measurement

By catheterization and viewing the urinary bag

Secondary outcomes

1

Description

CRP level

Timepoint

Before surgery, 6 hours after entering the Intensive Care Unit, 12 hours after and 24 hours after entering the Intensive Care Unit

Method of measurement

Blood Sample

2

Description

ESR level

Timepoint

Before surgery, 6 hours after entering the Intensive Care Unit, 12 hours after and 24 hours after entering the Intensive Care Unit

Method of measurement

Blood Sample

3

Description

Inotropic Score

Timepoint

In the Intensive Care Unit

Method of measurement

Inotropic score = ([dopamine + dobutamine]×1) + (milrinone×15) + ([epinephrine + norepinephrine + isoproterenol]×100)

Intervention groups

1

Description

Intervention group: At the end of the surgical procedure, before removing the aortic clamp, at the root of the aorta of patients, using a cardioplegia needle, a solution of dexmedetomidine with a concentration of 4 µg / ml, at a rate of 1 µg / kg / h, for 10 minutes, Is infused.

Category

Prevention

2

Description

Control group: At the end of the surgical procedure, before removing the aortic clamp, in the aortic root of patients, using a cardioplegia needle, 0.9% sodium chloride solution at a rate of 1 ml / kg / hour for 10 minutes infusion will be.

Category

Prevention

Recruitment centers

1

Recruitment center

Name of recruitment center

Imam Reza Heart Surgery Center, Mashhad, Iran

Full name of responsible person

Fateme Hajipour Aghmashhadi

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Imam Research and Treatment Center, Imam Reza Hospital Square, Ibne Sina St, Mashhad Town

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2

Recruitment center

Name of recruitment center

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Full name of responsible person

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Recruitment center

Name of recruitment center
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Sponsors / Funding sources

1

Sponsor

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presidentoffice@mums.ac.ir

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
Fateme Hajipour Aghmashhadi

Position
student

Latest degree
Bachelor

Other areas of specialty/work
perfusion

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Person responsible for scientific inquiries

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Position
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Latest degree
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Other areas of specialty/work
Perfusion

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Person responsible for updating data

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Latest degree

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Other areas of specialty/work

Perfusion

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Sharing plan

Deidentified Individual Participant Data Set (IPD)

Yes - There is a plan to make this available

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

Title and more details about the data/document

Will be published as an article

When the data will become available and for how long

One year

To whom data/document is available

Researchers and Experts

Under which criteria data/document could be used

it would be possible after getting permission from undersecretary of research

From where data/document is obtainable

send email to Hajipouraf981@mums.ac.ir

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

After requesting, the file will be sent in Excel or Spss.

Comments