

Clinical Trial Protocol

Iranian Registry of Clinical Trials

11 Sep 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 dexmedetomidine 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)

Phone

+98 11 3328 0646

Email address

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:

Supraventricular or 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

Mashhad

Province

Razavi Khorasan

Postal code

91177948064

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

I05.9

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 kinase _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 = $([\text{dopamine} + \text{dobutamine}] \times 1) + (\text{milrinone} \times 15) + ([\text{epinephrine} + \text{norepinephrine} + \text{isoproterenol}] \times 100)$

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

Street address

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

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Recruitment center

Name of recruitment center

Razavi Heart Surgery Center, Mashhad, Iran

Full name of responsible person

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Recruitment center

Name of recruitment center

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Full name of responsible person

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Sponsors / Funding sources

1

Sponsor

Name of organization / entity

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Full name of responsible person

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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

Street address

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Mazandaran

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Phone

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Hajipour_atena@yahoo.com

Person responsible for scientific 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 updating data

Contact

Name of organization / entity

Mashhad University of Medical Sciences

Full name of responsible person

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Position

Student

Latest degree

Bachelor

Other areas of specialty/work

Perfusion

Street address

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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