Clinical Trial Protocol
Iranian Registry of Clinical Trials

10 Jun 2026

Evaluation of the effect of adding dexmedetomidine to del-Nido cardioplegia solution on myocardial protection in patients undergoing mitral valve replacement / repair

Protocol summary

Study aim
Evaluation of the effect of adding dexmedetomidine to Del-Nido cardioplegia solution 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 an 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
Before administration of the cardioplegia solution, a vial of 200 µg / ml dexmedetomidine (in a 2 ml syringe labeled A) per 500 ml of Del-Nido cardioplegia solution will be added to the solution. The solution will contain dexmedetomidine at a concentration of 0.4 µg / ml. The infusion of the cardioplegia solution will be continued until complete cardiac arrest with the surgeon's advice. The amount and number of times the cardioplegia solution is administered will be recorded.

Main outcome variables
Troponin and CPK-MB changes

General information

Reason for update
Acronym
IRCT registration information
IRCT registration number: **IRCT20210713051881N1**
Registration date: **2021-11-03, 1400/08/12**
Registration timing: **prospective**

Last update: **2021-11-03, 1400/08/12**
Update count: **0**

Registration date
2021-11-03, 1400/08/12

Registrant information
Name
Pedram Chahi
Name of organization / entity
Country
Iran (Islamic Republic of)
Phone
+98 51 3760 3653
Email address
chahip981@mums.ac.ir

Recruitment status
Recruitment complete
Funding source

Expected recruitment start date
2021-11-22, 1400/09/01
Expected recruitment end date
2022-05-22, 1401/03/01
Actual recruitment start date
empty
Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Evaluation of the effect of adding dexmedetomidine to del-Nido cardioplegia solution 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:

History of supraventricular dysrhythmias History of heart surgery Nephropathy following the use of contrast agent (CIN) Persistent respiratory problems Patients with a history of Stroke and TIA Patients with a history of Coagulopathy Use an intra-aortic balloon pump (IABP) before and during surgery Use vasopressor before surgery Patient dissatisfaction to participate in the study The presence of any pathological disorder leading 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
- Investigator
- Data and Safety Monitoring Board

Sample size

Target sample size: **56**

Randomization (investigator's opinion)

Randomized

Randomization description

Using 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

The subjects, evaluators and analysts will be unaware of the solutions prescribed for the cardipoegy of the intervention and control groups. We will define the syringe containing the solutions with 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 Town۹۱۷۷۹۴۸۵۶۴

City

Mashhad

Province

Razavi Khorasan

Postal code

۹۱۷۷۹۴۸۵۶۴

Approval date

2021-06-15, 1400/03/25

Ethics committee reference number

IR.MUMS.MEDICAL.REC.1400.193

Health conditions studied

1

Description of health condition studied

Evaluation of the effect of adding dexmedetomidine to del-Nido cardioplegia solution on myocardial protection in patients undergoing mitral valve replacement / repair

ICD-10 code

I34

ICD-10 code description

Nonrheumatic mitral valve disorders

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 output

Timepoint

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

Method of measurement

By catheterization

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:Intervention group: Before administering the cardioplegia solution, a vial of 200 µg / ml dexmedetomidine (in a 2 ml syringe labeled A) per 500 ml of Del-Nido cardioplegia solution will be added to the solution. . The solution will contain dexmedetomidine at a concentration of 0.4 µg / ml. The infusion of the cardioplegia solution will be continued until complete cardiac arrest with the surgeon's advice. The amount and number of times the cardioplegia solution is administered will be recorded.

Category

Prevention

2

Description

Control group: Before administering the cardioplegia solution, 1ml of 0.9% sodium chloride solution (in a 2 ml syringe labeled B) will be added to the solution for every 500 ml of the Del-Nido cardioplegia solution. The infusion of the cardioplegia solution will be continued until complete cardiac arrest with the surgeon's advice. The amount and number of times the cardioplegia solution is administered will be recorded. The perfusionist will be unaware of the contents of the prescribed solution.

Category

Prevention

Recruitment centers

1

Recruitment center

Name of recruitment center

Imam Reza Heart Surgery Center, Mashhad, Iran

Full name of responsible person

Pedram Chahi

Street address

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
Shahid Rajaei Heart Surgery Center, Tehran, Iran

Full name of responsible person
Pedram Chahi

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Sponsors / Funding sources

1

Sponsor

Name of organization / entity
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Full name of responsible person
Majid Ghayyur Mobarhan

Street address
University St, Mashhad Town

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presidentoffice@mums.ac.ir

Web page address

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
Pedram Chahi

Position
Student

Latest degree
Bachelor

Other areas of specialty/work
perfusion

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Person responsible for scientific inquiries

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Other areas of specialty/work
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Person responsible for updating data

Contact

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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
It 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 the undersecretary of research

From where data/document is obtainable
Send email to chahip981@mums.ac.ir

What processes are involved for a request to access data/document
After request, the file will be sent in Excel or Spss.

Comments