

# Clinical Trial Protocol

## Iranian Registry of Clinical Trials

11 Sep 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](http://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](http://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 cardioplegia 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 Town 91177948064  
**City**  
Mashhad  
**Province**  
Razavi Khorasan  
**Postal code**  
91177948064

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

**Intervention groups**

**1**

**Description**

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

**City**

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**Email**

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**2**

**Recruitment center**

**Name of recruitment center**

Razavi Heart Surgery Center, Mashhad, Iran

**Full name of responsible person**

Pedram Chahi

**Street address**

Razavi Hospital, after Ghaem Bridge, Azadi Highway,  
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**3**

**Recruitment center**

**Name of recruitment center**

Shahid Rajaei Heart Surgery Center, Tehran, Iran

**Full name of responsible person**

Pedram Chahi

**Street address**

Shahid Rajaei Cardiovascular Training, Research and  
Treatment Center, next to Mellat Park- corner of  
Niayesh, Vali Asr St., Tehran Town

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**Sponsors / Funding sources**

**1**

**Sponsor**

**Name of organization / entity**

Mashhad University of Medical Sciences

**Full name of responsible person**

Majid Ghayyur Mobarhan

**Street address**

University St, Mashhad Town

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**Email**

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**

**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 updating data

**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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## 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