Clinical Trial Protocol
Iranian Registry of Clinical Trials

11 Jul 2026

Comparative study of the effect of milrinone and dobutamine on pulmonary hypertension after adult heart valve replacement surgery

Protocol summary

Study aim

Determining and comparing the effect of Milrinone and dobutamine on adult`s pulmonary hypertension after heart valve replacement surgery

Design

Clinical trial, consisting of two parallel groups receiving two different drug regimens, triple blinded, sample size of 38 patients, phase 3, randomized using random allocation software

Settings and conduct

In this study,38 patients suffering pulmonary hypertension who are candidates for heart valve replacement surgery in isfahan Shahid Chamran Heart hospital are randomly divided into two groups receiving milrinone (group 1) and dobutamine (group 2) using random allocation software. Systolic pulmonary arterial pressure (SPAP), Mean pulmonary arterial pressure (MPAP) and diastolic pulmonary arterial pressure (DPAP) are determined using echocardiography before surgery, then by implanting a pulmonary artery catheter، the above parameters are measured and recorded at the times after induction of anesthesia before Cardiopulmonary Bypass (CPB), after CPB, time to enter the Intensive care units(ICU) ،every 6 hours till 24 hours in the ICU and furthermore other parameters at the specific times.

Participants/Inclusion and exclusion criteria

Patients who are candidate for heart valve transplantation and suffering pulmonary hypertension The age over 18 years old The consent of patient to being involved ; Renal and hepatic failure Emergent surgery necessity to inotropic drugs before surgery Long QT interval patients Drug allergy

Intervention groups

The group that receiving milrinone infusion at a dose of 0.5 - 0.75 µg/kg/min and the group that receiving dobutamine 5-10 µg/kg/min infusion during 3 days of ICU hospitalization after surgery

Main outcome variables

Reduction of pulmonary hypertension, reduction of mechanical respiration, reduction of inotropic drug using duration, reduction of ICU hospitalization, reduction of tachycardia

General information

Reason for update

Hemodynamics of patients were maintained with the two main drugs of the study (milrinone and dobutamine), and because of professional and ethical reasons there was no need to use adjuvant and Additional drugs in most cases, so the title of the study is summarized as follows.

Acronym

IRCT registration information

IRCT registration number: **IRCT20211102052941N1**
Registration date: **2022-01-23, 1400/11/03**
Registration timing: **registered_while_recruiting**

Last update: **2022-07-15, 1401/04/24**
Update count: **1**

Registration date

2022-01-23, 1400/11/03

Registrant information

Name

Mohammad Mortazavi

Name of organization / entity

Country

Iran (Islamic Republic of)

Phone

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mormo1375@gmail.com

Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2022-01-12, 1400/10/22

Expected recruitment end date

2022-02-11, 1400/11/22

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Comparative study of the effect of milrinone and dobutamine on pulmonary hypertension after adult heart valve replacement surgery

Public title

Comparison of the effect of milrinone and dobutamine on pulmonary hypertension

Purpose

Treatment

Inclusion/Exclusion criteria

Inclusion criteria:

Patients who are candidate for heart valve transplantation and suffering pulmonary hypertension (right ventricular systolic pressure ≥50mmHg or meanPAP ≥40 mmHg or systolic PAP is mor than 50% of systemic systolic pressure) The age over 18 years old The consent of patient to being involved

Exclusion criteria:

Renal and hepatic failure Emergent surgery Necessity to inotropic drugs before surgery Long QT interval patients Drug allergy

Age

From **18 years** old

Gender

Both

Phase

3

Groups that have been masked

- Participant
- Care provider
- Outcome assessor
- Data analyser

Sample size

Target sample size: **38**

Randomization (investigator's opinion)

Randomized

Randomization description

This study is a randomized controlled clinical trial .before sampling, the order of assigning individuals to groups is determined randomly with random allocation software.In this way, before starting the sampling, patients are divided into two groups based on the Sequential turn number and as soon as they enter the study, they are assigned to one of the groups based on their turn number. In fact, patients are coded based on their turn number in the study and each code is randomly assigned to one of the groups. Individuals are assigned to groups by an operating room technologist outside the research team. The groups are marked with codes A and B and the researcher does not know the allocation of codes. Patients and the analyzer are also unaware of the medication received and the Drugs are blinded with names A and B. The group codes are opened after the analysis.

Blinding (investigator's opinion)

Triple blinded

Blinding description

Patients, clinical caregivers, outcome assessors, and data analyst are unaware of the medication regimen used in each patient group. In this way, the patients and drug regimens are divided into two groups A and B before entering the study and each patient receives the desired medication regimen according to that, which are blinded with the names A and B. The group codes are opened after the analysis.

Placebo

Not used

Assignment

Parallel

Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee

Ethics committee of Isfahan University of Medical Sciences

Street address

Hezar jerib Avenue, Isfahan, Isfahan Province

City

Isfahan

Province

Isfehan

Postal code

8168913866

Approval date

2021-01-25, 1399/11/06

Ethics committee reference number

IR.MUI.MED.REC.1399.980

Health conditions studied

1

Description of health condition studied

Pulmonary hypertension

ICD-10 code

I27.2

ICD-10 code description

Other secondary pulmonary hypertension

Primary outcomes

1

Description

Pulmonary blood pressure in millimeters of mercury

Timepoint

After induction of anesthesia, before CPB, after CPB, the ICU arrival moment and every 6 hours till 24 hours in ICU

Method of measurement

Pulmonary artery catheter

2

Description

Ejection fraction

Timepoint

Before surgery and 3 days after surgery

Method of measurement

Echocardiography

Secondary outcomes

empty

Intervention groups

1

Description

Intervention group 1:The group that receiving Intravenous infusion of milrinone at a dose of 0.5 - 0.75 µg / kg / min. Medication regimens commence from the time of patient`s rewarming and continue until the patient's condition stabilizes in the Intensive Care Unit under the anesthesia attending`s care .Milrinone is a phosphodiesterase III inhibitor commonly used after cardiopulmonary bypass in combination with adrenaline or noradrenaline µg/kg/min 0.1 - 0.5 to reduce pulmonary artery pressure with a synergistic inotropic effect. Noradrenaline made by BCWORLD PHARM CO. South Korea and Milrinon made by Baxter India.

Category

Treatment - Drugs

2

Description

Intervention group 2: The groupe that receiving Intravenous infusion of dobutamine 5-10 µg / kg / min. Dubotamine through strong agonist stimulation effect on Bradykinin 1 Receptor and moderate stimulation effect on Bradykinin 2 Receptor increases myocardial contractility and increases stroke volume, cardiac output and heart rate and decreases vascular resistance. After cardiac surgery, the combined use of dobutamine with Noradrenaline µg/kg/min 0.1 - 0.5 has more inotropic effect due to its competitive effect on Bradykinin 1 Receptor.Noradrenaline made by BCWORLD PHARM CO. South Korea and Dobutamine made by Darou Paksh-Iran.

Category

Treatment - Drugs

Recruitment centers

1

Recruitment center

Name of recruitment center

Shahid Chamran Heart Educational, Medical and Research Center

Full name of responsible person

Mohammadreza Shafiei

Street address

2nd Moshtagh St ,Isfahan , Isfahan Province

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Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Esfahan University of Medical Sciences

Full name of responsible person

Dr Mansour Siavash Dasjerdi

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Grant name

Grant code / Reference number

Is the source of funding the same sponsor organization/entity?

Yes

Title of funding source

Esfahan 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
Esfahan University of Medical Sciences

Full name of responsible person
Mojtaba Mansouri

Position
Associate Professor of Cardiac Anesthesia

Latest degree
Subspecialist

Other areas of specialty/work
Anesthesiology

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Shahid Chamran Hospital , Second Moshtagh Avenue , Isfahan

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Person responsible for scientific inquiries

Contact

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Sharing plan

Deidentified Individual Participant Data Set (IPD)
Yes - There is a plan to make this available

Study Protocol
Yes - There is 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
Yes - There is 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
All data from this study can be shared after Anonymizing individuals.

When the data will become available and for how long
Access starts after the results are published

To whom data/document is available
The data will be available only to researchers working in academic and scientific institutions

Under which criteria data/document could be used
The data of the present study can be used in any situation and anywhere

From where data/document is obtainable
Mojtaba Mansouri Mansouri@med.mui.ac.ir

What processes are involved for a request to access data/document
The documents and the file that can be published will be emailed immediately after verification, upon request of the applicant.

Comments