

Clinical Trial Protocol

Iranian Registry of Clinical Trials

27 May 2026

Comparison effect of nebulized milrinone and intravenous milrinone in patients with pulmonary hypertension who candidate of open-heart surgery

Protocol summary

Study aim

Comparison of the effect of nebulized milrinone and intravenous milrinone in patients with pulmonary hypertension who are candidates for open heart surgery

Design

After confirmation of pulmonary artery hypertension disorder, the admitted patients will be randomly assigned to open criculate ligament in two groups: A (Intratracheal milrinone) and B (Intravenous infusion of milrinone). The study is a clinical trial with a sample size of 16 people in parallel groups.

Settings and conduct

Patients referred to Ahvaz Golestan Hospital with a history of pulmonary artery hypertension undergoing open heart surgery are included in the study. Measurement of patient echocardiographic and hemodynamic factors such as: systolic blood pressure, diastolic blood pressure, mean arterial pressure (MAP), heart rate (HR), Systolic, diastolic, mean pulmonary artery pressure (MPAP), central venous pressure, systemic vascular resistance (SVR) and PVR, cardiac output, pulmonary indices and (SVR PVRI, SVRI) before and after surgery again in trimester 10, 30 and 60 minutes after surgery will also be measured.

Participants/Inclusion and exclusion criteria

patients with pulmonary hypertension enter the study field. If the patient refuses, the presence of COPD and pulmonary hemorrhage are excluded.

Intervention groups

1. Milrinone infusion group 0.5mcg/kg/min at the end of CPB pump
2. Group of administration of 5 cc milrinone intratracheal at the end of CPB pump

Main outcome variables

Pulmonary hypertension

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20201104049266N1**

Registration date: **2020-12-06, 1399/09/16**

Registration timing: **registered_while_recruiting**

Last update: **2020-12-06, 1399/09/16**

Update count: **0**

Registration date

2020-12-06, 1399/09/16

Registrant information

Name

sara Joreirahmadi

Name of organization / entity

Country

Iran (Islamic Republic of)

Phone

+98 61 3374 3017

Email address

sjaca4913@gmail.com

Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2020-11-21, 1399/09/01

Expected recruitment end date

2021-08-22, 1400/05/31

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Comparison effect of nebulized milrinone and intravenous milrinone in patients with pulmonary hypertension who candidate of open-heart surgery

Public title

effect of nebulized milrinone and intravenous milrinone in patients with pulmonary hypertension

Purpose

Treatment

Inclusion/Exclusion criteria

Inclusion criteria:

candidated for open heart surgery pulmonary pressure more than 40 mmhg 20 years <age <70 years

Exclusion criteria:

Patient refusal redo surgery COPD Kindey or Hepatic Failure LVEF<40mmhg Pulmonary bleeding in pulmonary HTN Mean pulmonary artery pressure>25mmhg

Age

From **20 years** old to **70 years** old

Gender

Both

Phase

N/A

Groups that have been masked

No information

Sample size

Target sample size: **16**

Randomization (investigator's opinion)

Randomized

Randomization description

Randomization was performed in a simple and individual manner with emphasis on the patient's case code and using a table of random numbers. In this method, all patients were coded and the code of each disease was randomly assigned to a group.

Blinding (investigator's opinion)

Not blinded

Blinding description

Placebo

Not used

Assignment

Parallel

Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee

Ethics committee of Ahwaz Jundishapur University of Medical SCIENCES

Street address

cardaic surgery or, Golestan Hospital, Golestan Blvd

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Province

Khouzestan

Postal code

6135733118

Approval date

2020-11-02, 1399/08/12

Ethics committee reference number

IR.AJUMS.REC.1399.654

Health conditions studied

1

Description of health condition studied

Pulmonary HTN

ICD-10 code

I27.2

ICD-10 code description

Other secondary pulmonary hypertension

Primary outcomes

1

Description

Mean pulmonary artery pressure

Timepoint

During surgery

Method of measurement

Using a radial artery catheter and a pulmonary artery catheter and through the left internal jugular vein

2

Description

Pulmonary capillary wedge pressure

Timepoint

During surgery

Method of measurement

Using a radial artery catheter and a pulmonary artery catheter and through the left internal jugular vein

Secondary outcomes

empty

Intervention groups

1

Description

Intervention group: Nebulized milrinone- In patients in this group, 2 mg of milrinone (dissolved in dextrose) is diluted in 3 ml of 9% sodium chloride and inhalation is complete within 15 minutes.

Category

Treatment - Drugs

2

Description

Control group: For patients in this group, 0.25-0.75 µg/kg/min milrinone will be injected intravenously.

Category

Treatment - Drugs

Recruitment centers**1****Recruitment center****Name of recruitment center**

Golestan hospital , Ahvaz Jondishapur University of Medical Sciences

Full name of responsible person

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Sponsors / Funding sources**1****Sponsor****Name of organization / entity**

Ahvaz University of Medical Sciences

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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

Ahvaz 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**

Ahvaz University of Medical Sciences

Full name of responsible person

Sara Joreirahmadi

Position

Assistant Professor

Latest degree

Subspecialist

Other areas of specialty/work

Anesthesiology

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Sharing plan**Deidentified Individual Participant Data Set (IPD)**

Undecided - It is not yet known if there will be a plan to make this available

Study Protocol

Undecided - It is not yet known if there will be a plan to make this available

Statistical Analysis Plan

Not applicable

Informed Consent Form

Undecided - It is not yet known if there will be a plan to make this available

Clinical Study Report

Not applicable

Analytic Code

Not applicable

Data Dictionary

Not applicable