

Clinical Trial Protocol

Iranian Registry of Clinical Trials

10 Jun 2026

Comparing the duration of CO₂ blowing into the surgical field during cardiac bypass on arterial carbon dioxide pressure in patients undergoing minimally invasive mitral valve repair

Protocol summary

Study aim

Comparing the duration of CO₂ blowing into the surgical field during cardiac bypass on arterial carbon dioxide pressure in patients undergoing minimally invasive mitral valve repair

Design

Clinical trial with control group, with parallel groups, randomized on 50 patients. Computer generated permutation blocks (www.sealedenvelope.com) will be used for randomization.

Settings and conduct

Patients who are candidates for minimally invasive mitral valve repair who visit Dena Hospital in Shiraz during the study will be included in the study if they are eligible and will be randomly assigned to the intervention and control groups using the random block method.

Participants/Inclusion and exclusion criteria

Inclusion criteria: patients between 20 and 55 years old, Patients who candidate for minimally invasive mitral valve repair and Patients with normal pulmonary status. Exclusion criteria: Positive history of liver and kidney failure, Positive history of Carotid artery stenosis, Positive history of brain diseases, Use of psychiatric medication and Alcoholic patients

Intervention groups

Control group (first group): In this study, all anesthesia conditions and settings of the pump device and prime oxygenator protocol are the same for all patients. In minimally invasive mitral valve repair, surgeons inject carbon dioxide gas throughout the procedure at a speed of 6 liters per minute, which increases the blood CO₂ level of patients during the bypass period. Intervention group (second group): In the patients of the second group, carbon dioxide injection is done only when rewarming the patient. With this timing, we try to reduce the related complications during cardiopulmonary bypass.

Main outcome variables

Arterial carbon dioxide pressure

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20230704058667N1**

Registration date: **2023-08-23, 1402/06/01**

Registration timing: **prospective**

Last update: **2023-08-23, 1402/06/01**

Update count: **0**

Registration date

2023-08-23, 1402/06/01

Registrant information

Name

Amirghofran Ahmad Ali

Name of organization / entity

Country

Iran (Islamic Republic of)

Phone

+98 71 3647 4270

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ghofran@sums.ac.ir

Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2023-09-01, 1402/06/10

Expected recruitment end date

2024-07-01, 1403/04/11

Actual recruitment start date

empty

Actual recruitment end date

empty
Trial completion date
empty

Scientific title
Comparing the duration of CO₂ blowing into the surgical field during cardiac bypass on arterial carbon dioxide pressure in patients undergoing minimally invasive mitral valve repair

Public title
Comparing the duration of CO₂ blowing into the surgical field during cardiac bypass on arterial carbon dioxide pressure in patients undergoing minimally invasive mitral valve repair

Purpose
Treatment

Inclusion/Exclusion criteria

Inclusion criteria:

patients between 20 and 55 years old
Patients who candidate for minimally invasive mitral valve repair
Patients with normal pulmonary status

Exclusion criteria:

Positive history of liver and kidney failure
Positive history of Carotid artery stenosis
Positive history of brain diseases
Use of psychiatric medication
Alcoholic patients

Age

From **20 years** old to **55 years** old

Gender

Both

Phase

2-3

Groups that have been masked

No information

Sample size

Target sample size: **50**

Randomization (investigator's opinion)

Randomized

Randomization description

Patients will be randomly allocated into two groups by block randomization. In this technique, a permutation block of size 4 and 6 will be made for patients of two groups A & B. In each block, equal numbers for two groups will be considered in alternative positions. Then 10 blocks will be selected randomly and patients will be allocated randomly and equally into two groups according to these permutation block. block sequence will be prepare by www.sealedenvelope.com.

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 Shiraz Medical School.

Street address

3rd Floor, 3rd buiding of the Shiraz Medical School, Zand Blvd.

City

Shiraz

Province

Fars

Postal code

7134844119

Approval date

2023-06-10, 1402/03/20

Ethics committee reference number

IR.SUMS.MED.REC.1402.125

Health conditions studied

1

Description of health condition studied

Mitral regurgitation

ICD-10 code

I34.0

ICD-10 code description

Nonrheumatic mitral (valve) insufficiency

Primary outcomes

1

Description

Arterial carbon dioxide pressure

Timepoint

10, 30, 60, 90 minutes after induction of anesthesia and day 1, 2, 3 of hospitalization in ICU

Method of measurement

Arterial blood pressure was measured using an arterial blood sample and a blood gas analyzer.

2

Description

Postoperative Delirium

Timepoint

first and 2nd postoperative day

Method of measurement

Delirium Screening Questionnaire (Nu-DESC)

Secondary outcomes

empty

Intervention groups

1

Description

Control group (first group): In this study, all anesthesia conditions and settings of the pump device and prime oxygenator protocol are the same for all patients. Also, the cardioplegia solution used in all patients is the same. In minimally invasive mitral valve repair (Minithoracotomy), surgeons inject carbon dioxide gas throughout the procedure at a speed of 6 liters per minute, which increases the blood CO₂ level of patients during the bypass period.

Category

Treatment - Surgery

2

Description

Intervention group (second group): our purpose in this study is to prevent the increase of CO₂ during cardiopulmonary bypass and also to reduce air embolism by changing the time of carbon dioxide gas injection in the chest cavity. In the patients of the second group, carbon dioxide injection is done only when rewarming the patient. With this timing, we try to reduce the related complications during cardiopulmonary bypass.

Category

Treatment - Surgery

Recruitment centers

1

Recruitment center

Name of recruitment center

Dena Hospital

Full name of responsible person

Mozhdeh Eskandari

Street address

Dena Hospital, Blvd-E-Sattar Khan, Zargari Blvd.

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7186764951

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Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Shiraz University of Medical Sciences

Full name of responsible person

Mohammad Hashem Hashempour

Street address

7th floor, central building of Shiraz University of

Medical Sciences, Vice Chancellor of research, Zand street.

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<https://rde.sums.ac.ir>

Grant name

Grant code / Reference number

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

No

Title of funding source

Shiraz 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

Shiraz University of Medical Sciences

Full name of responsible person

Mozhdeh Eskandari

Position

Master of Science student

Latest degree

Bachelor

Other areas of specialty/work

Hematology

Street address

Anesthesiology Department, Faghihi Hospital, Zand Street.

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1564471948

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Person responsible for scientific inquiries

Contact

Name of organization / entity

Shiraz University of Medical Sciences

Full name of responsible person

Ahmad Ali Amirghofran

Position

Associate Professor of Cardiovascular Surgery

Latest degree

Subspecialist

Other areas of specialty/work

Cardiology

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Person responsible for updating data

Contact

Name of organization / entity

Shiraz University of Medical Sciences

Full name of responsible person

Hamide Saeedizade

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Research Assistant

Latest degree

Bachelor

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Medical Informatics

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Sharing plan

Deidentified Individual Participant Data Set (IPD)

No - There is not a plan to make this available

Justification/reason for indecision/not sharing IPD

It is against our policy.

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