Clinical Trial Protocol
Iranian Registry of Clinical Trials

22 Nov 2026

Comparing the duration of CO۲ 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 CO۲ 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. Inminimally 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)
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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 CO_2 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 CO_2 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. Inminimally 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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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

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Person responsible for scientific inquiries

Contact

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Shiraz University of Medical Sciences

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Position
Associate Professor of Cardiovascular Surgery

Latest degree
Subspecialist

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Cardiology

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Person responsible for updating data

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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