

Clinical Trial Protocol

Iranian Registry of Clinical Trials

06 Jun 2026

The effect of moderate acidification of arterial blood pH by controlled inhalation of carbon dioxide on the rate of reperfusion injury in the early minutes after aortic clamp opening during heart valve surgery: A Pilot Study

Protocol summary

Study aim

If the right pH type is detected at the time of reperfusion, a more appropriate strategy can be adopted to reduce the complications of ischemia and reperfusion.

Design

Clinical trial with control group, with intervention groups, blind one-way, randomized with size 4 divided into 2 groups of 30 people. The randomization list is provided to the researcher in a sealed envelope.

Settings and conduct

This study is a single-blind randomized controlled clinical trial to evaluate the protective effect of acidic pH during primary cardiac reperfusion in patients undergoing elective open heart surgery, including valvular operations in the Shahid Rajaei Center.

Participants/Inclusion and exclusion criteria

No history of heart surgery, Left ventricular ejection fraction greater than 30% Hemoglobin above 10 milligram per deciliter No kidney or liver dysfunction Lack of impaired lung function tests

Intervention groups

patients are divided into two groups: the group with a pH above 7.35 and the group with a pH below 7.35. The group with acidic pH is excluded from the study, but in the normal pH group, patients are divided into two groups by block randomization: one group is kept in the same normal pH and in the second group the pH is maintained by performing Intervention and change in Pco₂(Partial Pressure of Carbon Dioxide) It becomes acidic to Reach the desired pH of 7.30 to 7.25 to prevent the pH paradox onset of reperfusion and continue for 2 minutes after aortic declamping.

Main outcome variables

Determining and comparing the average ejection fraction Determination and comparison of mean levels of cardiac enzymes (troponin, Creatine kinase-MB, Lactate

Dehydrogenase) Determining and comparing the mean level of malonyl dioxide as the main biomarker of oxidative stress, nitric oxide (NO) production level, glutathione peroxidase and superoxide dismutase levels before and after aortic clamp opening

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20211101052940N1**

Registration date: **2022-02-05, 1400/11/16**

Registration timing: **prospective**

Last update: **2022-02-05, 1400/11/16**

Update count: **0**

Registration date

2022-02-05, 1400/11/16

Registrant information

Name

aregnia minasians

Name of organization / entity

Rajaie Cardiovascular, Medical and Research Center

Country

Iran (Islamic Republic of)

Phone

+98 21 7753 3097

Email address

aregnia_minasians@rhc.ac.ir

Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2022-02-20, 1400/12/01
Expected recruitment end date
2022-07-22, 1401/04/31
Actual recruitment start date
empty
Actual recruitment end date
empty
Trial completion date
empty

Scientific title

The effect of moderate acidification of arterial blood pH by controlled inhalation of carbon dioxide on the rate of reperfusion injury in the early minutes after aortic clamp opening during heart valve surgery: A Pilot Study

Public title

The effect of moderate acidification of arterial blood pH by controlled inhalation of carbon dioxide on the rate of reperfusion injury in the early minutes after aortic clamp opening during heart valve surgery: A Pilot Study

Purpose

Prevention

Inclusion/Exclusion criteria

Inclusion criteria:

Patient consent to study Age over 18 years and under 65 years No history of sternotomy and heart surgery Left ventricular ejection fraction greater than 30% Pulmonary outflow volume with pressure per second (FEV1) greater than 65% in spirometry Hemoglobin above 10 mg per deciliter

Exclusion criteria:

Need for drug support (receiving inotropes before starting heart surgery) Having a pacemaker or ICD(Implantable Cardioverter Defibrillator) Having impaired lung function tests for FEV1 less than 40% Having kidney or liver dysfunction

Age

From **18 years** old to **65 years** old

Gender

Both

Phase

N/A

Groups that have been masked

- Care provider

Sample size

Target sample size: **60**
More than 1 sample in each individual
Number of samples in each individual: **4**
5 minutes before the aortic clamp opens and 5 minutes after the aortic clamp opens

Randomization (investigator's opinion)

Randomized

Randomization description

Patients are divided into two groups of 30 based on randomized block size 4. A list of how patients are crashed into a closed envelope is provided to the researcher and patients are assigned to each of the intervention and control groups before the aortic clamp is opened. Performed by the researcher.

Blinding (investigator's opinion)

Single blinded

Blinding description

In this study, the intensive care unit nurse who is responsible for caring for the patient is kept blind.

Placebo

Not used

Assignment

Other

Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee

Ethics committee of Rajaie cardiovascular, medical and research center

Street address

Bell 7, No. 14, Shahid Javadnia St, Bahar Shiraz St, 7th Tir Square

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Tehran

Province

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1564738719

Approval date

2021-09-08, 1400/06/17

Ethics committee reference number

IR.RHC.REC.1400.029

Health conditions studied

1

Description of health condition studied

The effect of moderate arterial blood acidosis during reperfusion in valvular heart surgery

ICD-10 code

I38

ICD-10 code description

Endocarditis, valve unspecified

Primary outcomes

1

Description

Type of heart rhythm

Timepoint

After removal of the aortic clamp

Method of measurement

ECG curve shape and heart rate per minute

2

Description

Return time of sinus rhythm of the heart

Timepoint

After removal of the aortic clamp

Method of measurement

Minutes

3

Description

Need for antiarrhythmic drugs

Timepoint

After removal of the aortic clamp

Method of measurement

Yes or no

4

Description

Consumption of inotropic after opening the aortic clamp

Timepoint

After removal of the aortic clamp

Method of measurement

Micrograms per kilogram per hour

5

Description

Requires defibrillator

Timepoint

After removal of the aortic clamp

Method of measurement

Yes or no

6

Description

Need a pacemaker

Timepoint

After removal of the aortic clamp

Method of measurement

Yes or no

7

Description

The amount of lactate

Timepoint

After separation of cardiopulmonary bypass machine

Method of measurement

Mg per liter

8

Description

Cardiac enzymes (troponin, Lactate Dehydrogenase and Creatine kinase-MB levels)

Timepoint

Before surgery, 12 and 24 hours after surgery

Method of measurement

Micrograms per deciliter

9

Description

Heart ejection fraction

Timepoint

Before and after surgery

Method of measurement

Echo of the heart and in percent

10

Description

Glutathione peroxidase and superoxide dismutase enzymes

Timepoint

Before the aortic clamp and 5 minutes after the opening of the aortic clamp from the coronary sinus

Method of measurement

coronary sinus blood samples in units per liter

11

Description

Malonyl di aldehyde

Timepoint

Before the aortic clamp and 5 minutes after the opening of the aortic clamp from the coronary sinus

Method of measurement

Micromol per deciliter

12

Description

Nitric oxide

Timepoint

Before the aortic clamp and 5 minutes after the opening of the aortic clamp from the coronary sinus

Method of measurement

Micromol per deciliter

13

Description

Duration of mechanical ventilation

Timepoint

Duration of the patient's arrival after surgery to the intensive care unit

Method of measurement

Hour

14

Description

Stay in the intensive care unit

Timepoint

Duration of the patient arrival after surgery to the intensive care unit until to get out of it

Method of measurement

Hour

Secondary outcomes

1

Description

Blood pressure

Timepoint

During the injection of carbon dioxide

Method of measurement

Mm of mercury

Intervention groups

1

Description

Intervention group: Temporary respiratory acidosis is induced for the reperfusion phase by intentional inhalation of Carbon dioxide gas into the oxygenator, and therapeutic hypercapnia (partial pressure of carbon dioxide = 50-60) is performed to establish a pH in the range of 7.25 to 7.30. In contrast, 6 minutes before reperfusion, gas is added to the mixture of oxygen and air, and after opening the aortic clamp, it continues for 2 minutes after reperfusion.

Category

Prevention

2

Description

Control group: In this group of patients, reperfusion will be performed with normal pH, ie between 7.35 and 7.45.

Category

Prevention

Recruitment centers

1

Recruitment center

Name of recruitment center

Shahid Rajaei Cardiovascular Hospital

Full name of responsible person

Doctor Saeed Hosseini

Street address

Next to Mellat Park, Vali Asr Ave, Tehran, IRAN.

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Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Shahid Rajaei Cardiovascular Hospital

Full name of responsible person

Doctor Saeed Hosseini

Street address

2nd Floor, operating room, corner of Niayesh, next to Mellat Park, Vali Asr St. (AS)

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Web page address

<http://rhc.ac.ir/fa>

Grant name

Grant code / Reference number

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

Yes

Title of funding source

Shahid Rajaei Cardiovascular Hospital

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

Shahid Rajaie cardiovascular, medical and research center

Full name of responsible person

Aregnia Minasians

Position

Master student of perfusion

Latest degree

Bachelor

Other areas of specialty/work

Others

Street address

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Person responsible for scientific inquiries

Contact

Name of organization / entity
Shahid Rajaei Cardiovascular Hospital
Full name of responsible person
Doctor Seyed Saeed Hosseini
Position
Professor
Latest degree
Subspecialist
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specialty Cardiac Surgery
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Person responsible for updating data

Contact

Name of organization / entity
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Master student of perfusion
Latest degree
Bachelor
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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

Based on the consent obtained from patients, their information remains confidential.

Study Protocol

Yes - There is a plan to make this available

Statistical Analysis Plan

Yes - There is a plan to make this available

Informed Consent Form

Yes - There is a plan to make this available

Clinical Study Report

Yes - There is a plan to make this available

Analytic Code

Yes - There is a plan to make this available

Data Dictionary

Yes - There is a plan to make this available

Title and more details about the data/document

In this study, the names and surnames of the individuals remain confidential, but the results of the study and their consequences are shared.

When the data will become available and for how long

Approximately 6 months from the time of sampling

To whom data/document is available

Data only for researchers working in academic and scientific institutions

Under which criteria data/document could be used

After completing the work and publishing the dissertation at the university. Those who want to have access please refer to the center library.

From where data/document is obtainable

After completing the work and publishing the dissertation at the university. Those who want to have access please refer to the center library.

What processes are involved for a request to access data/document

After completing the work and publishing the dissertation at the university. Those who want to have access please refer to the center library.

Comments