Clinical Trial Protocol
Iranian Registry of Clinical Trials

07 Jun 2026

The effect of moderate acidification of arterial blood pH on the rate of miR-499 Biomarker level in the early minutes after aortic clamp opening during heart valve surgery: A Pilot Study

Protocol summary

Study aim

The effect of moderate acidification of arterial blood pH on the miR-499 biomarker level (one of the cardiomyocard protection factors after reperfusion) in the first minutes after opening the aortic clamp in order to reduce the complications of 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

miR-499, Type of heart rhythm, Return time of sinus rhythm of the heart, Consumption of inotropic after opening the aortic clamp, The amount of lactate, Cardiac enzymes (troponin, Lactate Dehydrogenase and Creatine kinase-MB levels), Need for antiarrhythmic drugs, Heart ejection fraction

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20211101052940N2**
Registration date: **2023-04-14, 1402/01/25**
Registration timing: **registered_while_recruiting**

Last update: **2023-04-14, 1402/01/25**
Update count: **0**

Registration date

2023-04-14, 1402/01/25

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

2022-12-01, 1401/09/10

Expected recruitment end date

2023-06-20, 1402/03/30

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 on the rate of miR-499 Biomarker level 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 on the rate of miR-499 Biomarker level in the early minutesafter 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: **2**
5 minutes before the aortic clamp opens and 5 minutes after the aortic clamp opens
Randomization (investigator's opinion)
Randomized
Randomization description
The patients were divided into 2 groups of 30 people using the computer program CREATE A RANDOMISATION LIST, in the form of block randomization with a size of 4. Thus, 15 blocks of 4 were obtained, and in each block, 2 patients were randomly assigned to the intervention group and 2 patients to the control group. In each block, the permutations created were in the form of AABB, ABAB, ABBA, BBAA, ... where each A was the sign of the intervention group and the letter B was the sign of the control group.
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
Parallel
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
Next to Mellat Park, Vali Asr Ave, Tehran, IRAN.
City
Tehran
Province
Tehran
Postal code
1995614331
Approval date
2021-07-31, 1400/05/09
Ethics committee reference number
IR.RHC.REC.1400.035

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
ICD-10 code description

Primary outcomes

1

Description
miR-499
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 mili liter

2

Description
Type of heart rhythm

Timepoint
After removal of the aortic clamp
Method of measurement
ECG curve shape and heart rate per minute

3

Description
Return time of sinus rhythm of the heart
Timepoint
After removal of the aortic clamp
Method of measurement
seconds

4

Description
Consumption of inotropic after opening the aortic clamp
Timepoint
After removal of the aortic clamp
Method of measurement
Yes or no

5

Description
The amount of lactate
Timepoint
After separation of cardiopulmonary bypass machine
Method of measurement
Mg per liter

6

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

7

Description
Need for antiarrhythmic drugs
Timepoint
After removal of the aortic clamp
Method of measurement
Yes or no

8

Description
Heart ejection fraction
Timepoint
Before and after surgery
Method of measurement
Echo of the heart and in percent

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, 5 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 the control group, blood re-perfusion to the heart is performed after opening the aortic clamp, with a pH in the normal range, i.e. 7.35 to 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.
City
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Email
aregnia_minasians@yahoo.com
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http://rhc.ac.ir/fa

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
Shahid Rajaei valvular heart disease research center
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 of Perfusion
Latest degree
Master
Other areas of specialty/work
perfusionist
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Person responsible for scientific inquiries

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Full name of responsible person
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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
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 10 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 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 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 at the university. Those who want to have access please refer to the center library.
Comments