Clinical Trial Protocol
Iranian Registry of Clinical Trials

17 Sep 2026

Evaluation the effects of controlled aortic root reperfusion with and without adenosine on clinical outcome in patients undergoing heart valve surgery

Protocol summary

Study aim
Assessing the effect of aortic root controlled reperfusion with and without adenosine on postoperative outcome after valvular surgery

Design
Randomized double-blind phase 3 clinical trial on 60 patients, with block randomization

Settings and conduct
This randomized double-blind clinical trial will conduct at Rajaei Cardiovascular center in 2022. The randomization will conduct by block randomization in a 1:1 allocation and patients will receive/not receive adenosine after off-pumping following valvular surgery.

Participants/Inclusion and exclusion criteria
Inclusion criteria: patients aged between 18-65, with no pacemakers, no ICD, and no need of inotropes, which undergone valvular heart surgery for the first time, and need a cardiopulmonary bypass, aortic cross-clamp, and cardioplegia, and EF more than 35%, lack of ventricular hypertrophy, pulmonary artery pressure less than 65 in their perioperative echocardiography. Exclusion criteria: the need for cardiopulmonary bypass after off-pumping, the need for Intra aortic balloon pump, the need for mechanical heart support.

Intervention groups
In the intervention group: before off-pomping, warmblood with adenosine will be administered in a dose of 150 micrograms/kg (maximum dose: 12 milligrams) during 5-25 minutes (based on the return of cardiac contraction), in the volume of 200-250cc per minute, with the pressure of 30-50mm Hg by the roller pump through the cardioplegic line. In the control group, warmblood without adenosine will be administered in the same protocol as the intervention group.

Main outcome variables
Need for inotropic drugs; Need for anti-arrhythmia drugs; Need for the defibrillator for off-pumping; Cross-clamp time

General information

Reason for update

Acronym

IRCT registration information
IRCT registration number: **IRCT20211225053519N1**
Registration date: **2022-01-03, 1400/10/13**
Registration timing: **prospective**

Last update: **2022-01-03, 1400/10/13**
Update count: **0**

Registration date
2022-01-03, 1400/10/13

Registrant information

Name
Mohammad Amin Shahrbaf

Name of organization / entity
Royan Institute

Country
Iran (Islamic Republic of)

Phone
+98 21 4496 0244

Email address
aminshahrbaf41@gmail.com

Recruitment status
Recruitment complete

Funding source

Expected recruitment start date
2022-02-04, 1400/11/15

Expected recruitment end date
2022-03-06, 1400/12/15

Actual recruitment start date
empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Evaluation the effects of controlled aortic root reperfusion with and without adenosine on clinical outcome in patients undergoing heart valve surgery

Public title

Effects of adenosine in controlled reperfusion after heart valvular surgery

Purpose

Treatment

Inclusion/Exclusion criteria

Inclusion criteria:

Elective (not emergency) valvular surgery Cardiopulmonary bypass, and need for aortic cross-clamp and cardioplegia during operation Ejection fraction more than 35% before the surgery Negative history for previous cardiac surgery Lack of ventricular hypertrophy based on the preoperative echocardiography Lack of Inotropic consumption before the operation Lack of pacemakers or implantable cardioverter-defibrillator Pulmonary artery pressure less than 65mm Hg Filling the informed consent form

Exclusion criteria:

Returning to cardiopulmonary bypass during the operation Need for intra aortic balloon pump Need for mechanical heart support

Age

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

Gender

Both

Phase

3

Groups that have been masked

- Participant
- Outcome assessor
- Data analyser

Sample size

Target sample size: **60**

Randomization (investigator's opinion)

Randomized

Randomization description

In this study, we will use the block randomization method. Blocking is usually used to balance the number of samples assigned to each study group. The size of all the blocks in this study is equal, and we will have a 4-person block size (two interventions and two controls). Random allocation software is also used as the randomization tool. The allocation concealment will be used for hiding so that the assigned group is not known before the individual is assigned. Using opaque envelopes sealed with random sequences, each of the random sequences created is recorded on a card, and the cards are placed in the envelopes, respectively. To maintain a random series, the envelopes are numbered in the same way on the outer surface. Finally, the lids of the envelopes are glued and placed in a box, respectively. At the beginning of the registration of participants, based on the order of entry of eligible participants into the study, one of the envelopes of the letter is opened in order, and the assigned group of the participant is revealed.

Blinding (investigator's opinion)

Double blinded

Blinding description

Each group will have a specific code and patients, outcome assessor, and data analyzer will not be informed of the intervention.

Placebo

Not used

Assignment

Parallel

Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee

Research Ethics Committees of Rajaie Cardiovascular Medical and Research Center

Street address

Shahid Rajaei Cardiovascular Center, Next to Mellat Park, Vali-Asr Ave, Tehran, Iran.

City

Tehran

Province

Tehran

Postal code

199697751

Approval date

2020-06-27, 1399/04/07

Ethics committee reference number

IR.RHC.REC.1399.041

Health conditions studied

1

Description of health condition studied

Surgery of the valvular heart disease

ICD-10 code

I05-I09, Q

ICD-10 code description

Chronic rheumatic heart diseases, Congenital malformations of the circulatory system

Primary outcomes

1

Description

Need for inotropic or anti arrhythmic drugs

Timepoint

Immediately after the surgery, during ICU stay

Method of measurement
Assessing receive/not receiving inotropic or anti arrhythmic drugs based on the medical record during the hospitalization

2

Description
Use of defibrillator
Timepoint
Immediately after the surgery
Method of measurement
Assessing the need for defibrillator based on the medical record during the hospitalization

3

Description
Type and time of the reentry rhythm
Timepoint
Immediately after the surgery
Method of measurement
Cardiac monitoring

4

Description
Cardiopulmonary Bypass Time
Timepoint
During the operation
Method of measurement
Time of the cardiopulmonary bypass in minutes

5

Description
Aortic Cross Clamp Time
Timepoint
During the operation
Method of measurement
Time of the aortic cross clamp in minutes

6

Description
ICU stay
Timepoint
After the operation
Method of measurement
ICU stay based on days

7

Description
Mechanical Ventilation time
Timepoint
During the operation
Method of measurement
Mechanical ventilation time in minute

8

Description
Troponin laboratory assessment
Timepoint
After the operation
Method of measurement
Biochemical assessment

9

Description
CPK assessment
Timepoint
After the operation
Method of measurement
Biochemical analysis

10

Description
Renal function assessment
Timepoint
After the operation
Method of measurement
Biochemical Assessment

11

Description
Liver function assessment
Timepoint
After the operation
Method of measurement
Biochemical assessment

Secondary outcomes

empty

Intervention groups

1

Description
Intervention group: In the intervention group and before off-pumping, warmblood with adenosine will be administered in a dose of 150 micrograms/kg (maximum dose: 12 milligrams), during 5-25 minutes (based on the return of cardiac contraction), in the volume of 200-250cc per minute, with the pressure of 30-50mm Hg by the roller pump through the cardioplegic line.
Category
Treatment - Drugs

2

Description
Control group: In the control group and before off-pumping, warmblood without adenosine will be administered during 5-25 minutes (based on the return of cardiac contraction), in the volume of 200-250cc per minute, with the pressure of 30-50mm Hg by the roller pump through the cardioplegic line.
Category
Treatment - Drugs

Recruitment centers

1

Recruitment center

Name of recruitment center
Rajaei Cardiovascular Medical, Educational and Research Center

Full name of responsible person
Feridoon Nouhi

Street address
Rajaei Cardiovascular Medical, Educational and Research Center, Next to Mellat Park, Vali-Asr Ave, Tehran, Iran

City
Tehran

Province
Tehran

Postal code
199697751

Phone
+98 21 23921

Email
info@rhc.ac.ir

Web page address

Sponsors / Funding sources

1

Sponsor

Name of organization / entity
Iran University of Medical Sciences

Full name of responsible person
Feridoon Nouhi

Street address
Shahid Rajaei Research & Training Hospital, Next to Mellat Park, Vali-Asr Ave, Tehran, IRAN.

City
Tehran

Province
Tehran

Postal code
199697751

Phone
+98 21 23921

Email
info@rhc.ac.ir

Grant name

Grant code / Reference number

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

Title of funding source
Iran 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
Iran University of Medical Sciences

Full name of responsible person
Mohammad Amin Shahrbaf

Position
Research Assistant

Latest degree
Medical doctor

Other areas of specialty/work
Cardiology

Street address
Shahid Rajaei Research & Training Hospital, Next to Mellat Park, Vali-Asr Ave, Tehran, IRAN.

City
Tehran

Province
Tehran

Postal code
199697751

Phone
+98 21 23921

Email
Aminshahrbaf41@gmail.com

Person responsible for scientific inquiries

Contact

Name of organization / entity
Iran University of Medical Sciences

Full name of responsible person
Mohammad Amin Shahrbaf

Position
Research Assistant

Latest degree
Medical doctor

Other areas of specialty/work
Cardiology

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Email
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Person responsible for updating data

Contact

Name of organization / entity
Iran University of Medical Sciences

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Sharing plan

Deidentified Individual Participant Data Set (IPD)
Yes - There is a plan to make this available

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
All Deidentified Individual Participant Data Set will be available after the end of the study

When the data will become available and for how long
6 month after publishing the results

To whom data/document is available
Researchers who work in academic institute

Under which criteria data/document could be used
Data is given to the researchers just for assessment and not for interfering

From where data/document is obtainable
Through email: Me_service22@yahoo.com

What processes are involved for a request to access data/document
The data will given to researchers after assessing the eligibility through email

Comments