# Clinical Trial Protocol
# Iranian Registry of Clinical Trials

29 Jun 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)

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**Email address**
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**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

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**Phone**
+98 21 23921

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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**
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**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

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## Person responsible for scientific inquiries

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**Other areas of specialty/work**
Cardiology

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## Person responsible for updating data

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**Latest degree**
Medical doctor

**Other areas of specialty/work**
Cardiology

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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**