

Clinical Trial Protocol

Iranian Registry of Clinical Trials

24 Jul 2026

The effect of adenosine in cold blood cardioplegia on cardiac function and ischemia- reperfusion injury in patients undergoing heart valve surgery

Protocol summary

Study aim

The effect of adenosine in cold blood cardioplegia on cardiac function and ischemia- reperfusion injury in patients undergoing heart valve surgery

Design

This study is a double blind randomized clinical trial that involved all patients with mitral valve disease during year 2016

Settings and conduct

The study is being carried out at Shahid Rajaei Hospital. 40 patients were randomly divided into two groups, after the heart-lung machine connected to the patient, cold blood cardioplegia solution (4 C °) injected into the aortic root antegrade (15 CC / Kg).

Participants/Inclusion and exclusion criteria

patients' willingness to participate in research; written informed consent; all of patients with mitral valve disease. Exclusion criteria: patients with aortic valve disease; pulmonary disease; two valves diseases; coronary heart disease; liver disease; kidney disease; lung disease; high blood pressure; diabetes; asthma; heart surgery; cardiac output less than 30%; history of adenosine-sensitivity and all the patients had a previous surgical history

Intervention groups

To immobilize the heart in the control group hyperkalemic cardioplegic solution add and hyperkalemic cardioplegic solution with adenosine 2 mM will be used in the intervention group. Main outcome measures variables: TNF- α , Troponin, LDH, CPK-mb, Ca

Main outcome variables

TNF- α

General information

Reason for update

Change the location of the project

Acronym

IRCT registration information

IRCT registration number: **IRCT2016061428454N1**

Registration date: **2016-07-20, 1395/04/30**

Registration timing: **prospective**

Last update: **2019-11-13, 1398/08/22**

Update count: **1**

Registration date

2016-07-20, 1395/04/30

Registrant information

Name

Atefeh Asadmobini

Name of organization / entity

Kermanshah University of Medical Science,
Cardiovascular Research Centre

Country

Iran (Islamic Republic of)

Phone

+98 83 3839 5970

Email address

aasadmobini@kums.ac.ir

Recruitment status

Recruitment complete

Funding source

kermanshah university of medical science

Expected recruitment start date

2018-12-22, 1397/10/01

Expected recruitment end date

2019-12-22, 1398/10/01

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

The effect of adenosine in cold blood cardioplegia on cardiac function and ischemia- reperfusion injury in

patients undergoing heart valve surgery

Public title
The effect of adenosine in cardioplegic solution

Purpose
Prevention

Inclusion/Exclusion criteria
Inclusion criteria:
 patients' willingness to participate in research; written informed consent; all of patients with mitral valve disease. Exclusion criteria: patients with aortic valve disease; pulmonary disease; two valves diseases; coronary heart disease; liver disease; kidney disease; lung disease; high blood pressure; diabetes; asthma; heart surgery; cardiac output less than 30%; history of adenosine-sensitivity and all the patients had a previous surgical history.
Exclusion criteria:

Age
From **30 years** old to **65 years** old

Gender
Both

Phase
2-3

Groups that have been masked

- Participant
- Investigator

Sample size
Target sample size: **40**

Randomization (investigator's opinion)
Randomized

Randomization description
Forty patients were randomly divided into two groups and matched for severity of disease and compared in each group of patients with the same severity (stenosis, dilation, failure, repair and replacement).

Blinding (investigator's opinion)
Single blinded

Blinding description
The patient, surgeon, and physician responsible for evaluating the patient are not aware of the type of treatment

Placebo
Not used

Assignment
Parallel

Other design features

Secondary Ids
empty

Ethics committees

1

Ethics committee
Name of ethics committee
 Ethic committee of Rajaei cardiovascular Medical and research center
Street address

Ethic committee of Rajaei cardiovascular Medical and research center

City
Tehran

Province
Tehran

Postal code
1995614331

Approval date
2018-04-28, 1397/02/08

Ethics committee reference number
IR-RHC-REC-1397-007

Health conditions studied

1

Description of health condition studied

Mitral valve surgery

ICD-10 code

I05.8

ICD-10 code description

Mitral (valve) failure

Primary outcomes

1

Description

TNF- α

Timepoint

Before and after the intervention.

Method of measurement

Laboratory analysis of blood samples

Secondary outcomes

1

Description

Hemodynamic parameters

Timepoint

1. Basic 2-15 minutes after CPB 3-6 hours after CPB 4-24 hours after CPB

Method of measurement

Heart rhythm ECG, Blood pressure by artelain, CVP transducer dome

Intervention groups

1

Description

In order to immobilize the heart in the intervention group, hyperkalemic cardioplegic solution with adenosine 2 mM will be used in the intervention group.

Category

Treatment - Surgery

2

Description

In order to immobilize the heart hyperkalemic cardioplegic solution will be used in the control group.

Category

Treatment - Surgery

Recruitment centers

1

Recruitment center

Name of recruitment center

Rajae Hospital

Full name of responsible person

Dr Alireza Alizadeh Ghavidel

Street address

Tehran- Rajae Cardiovascular and medical research center

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aaghavidel@gmail.com

Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Rajae hospital

Full name of responsible person

Dr Alireza Alizadeh Ghavidel

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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

Rajae 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

Rajae Hospital

Full name of responsible person

Fahimeh Ghasemi

Position

Researcher

Latest degree

Master

Other areas of specialty/work

Researcher

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Cardiovascular Research Centre, Shahid Rajae Hospital, Tehran, Iran

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Person responsible for scientific inquiries

Contact

Name of organization / entity

rajaee cardiovascular medical and research center

Full name of responsible person

Dr Alireza Alizadeh Ghavidel

Position

Cardiac surgeon

Latest degree

Subspecialist

Other areas of specialty/work

surgery

Street address

rajaee cardiovascular medical and research center

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Person responsible for updating data

Contact

Name of organization / entity
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Other areas of specialty/work
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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

the data has been report as a article

When the data will become available and for how long

after data collection

To whom data/document is available

The data are available to the study researchers.

Under which criteria data/document could be used

The data are available to the study researchers.

From where data/document is obtainable

Rajae Hospital

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

Must be part of the research project.

Comments