

Clinical Trial Protocol

Iranian Registry of Clinical Trials

16 Jul 2026

The Comparison of the effect of Antegrade and Antegrade-Retrograde blood cardioplegia approach on paradoxical septal motion after coronary artery bypass graft

Protocol summary

Study aim

The comparison of the effect of antegrade and antegrade-retrograde blood cardioplegia approach on paradoxical septal motion after heart surgery.

Design

A clinical trial with two groups of 36 people comparing the effects of two methods: three way blinded ,randomized with coin tossing

Settings and conduct

This study is performed in patients referred to Isfahan Chamran Hospital. The cannula is implanted by a heart surgeon. The cardioplegia solution is injected by a perfusionist with pressure control. It is performed after surgery and before discharge echocardiography . The paradoxical septum is examined, and patients and the evaluator of the effect of the intervention and the data analyzer did not know in which group the samples were.

Participants/Inclusion and exclusion criteria

1. Being 45 to 65 years old 2-EF more than 50 percent in preoperative echocardiography 3. No septal movement disorder in preoperative echocardiography 4. No history of myocardial infarction 5. No aortic valve insufficiency in preoperative echocardiography 6. Lack of internal heart pacemaker

Intervention groups

Patients who are candidates for coronary artery bypass graft surgery in terms of cardioplegia method are divided into two groups: antegrade, which is implanted in the aortic root, and antegrade-retrograde group, which is injected in both the aortic root and coronary sinus in reverse anatomical blood flow of cardioplegia solution. .

Main outcome variables

The measurable variable is the paradoxical septal motion, which is a measure of the lack of proper cardiac protection during surgery.

General information

Reason for update

Acronym

psm

IRCT registration information

IRCT registration number: **IRCT20170620034666N5**

Registration date: **2022-03-16, 1400/12/25**

Registration timing: **retrospective**

Last update: **2022-03-16, 1400/12/25**

Update count: **0**

Registration date

2022-03-16, 1400/12/25

Registrant information

Name

Mehran Shahzamani

Name of organization / entity

Isfahan university of medical science

Country

Iran (Islamic Republic of)

Phone

+98 31 3670 1227

Email address

m.shahzamani@med.mui.ac.ir

Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2021-06-05, 1400/03/15

Expected recruitment end date

2022-01-05, 1400/10/15

Actual recruitment start date

2021-06-05, 1400/03/15

Actual recruitment end date

2022-01-05, 1400/10/15

Trial completion date

2022-01-15, 1400/10/25

Scientific title

The Comparison of the effect of Antegrade and Antegrade-Retrograde blood cardioplegia approach on paradoxical septal motion after coronary artery bypass graft

Public title

The effect of cardioplegia on paradoxical septal motion

Purpose

Prevention

Inclusion/Exclusion criteria**Inclusion criteria:**

Being 45 to 65 years old EF more than 50% in preoperative echocardiography No septal movement disorder in preoperative echocardiography No history of myocardial infarction No aortic valve insufficiency in preoperative echocardiography Lack of internal heart pacemaker No absence of right or left branch block in the ECG after cardiac surgery Absence of intraventricular conduction delay (IVCD) in preoperative ECG

Exclusion criteria:

The unwillingness of the patient or companions to participate in the study Existence of shunt inside the heart The presence of right and left branch blocks in the ECG before surgery

Age

From **45 years** old to **65 years** old

Gender

Both

Phase

N/A

Groups that have been masked

- Participant
- Care provider
- Outcome assessor
- Data analyser

Sample size

Target sample size: **72**

Actual sample size reached: **72**

Randomization (investigator's opinion)

Randomized

Randomization description

The simple randomization method was performed by tossing coins between the samples that met the inclusion criteria, considering that there were two groups in the study.

Blinding (investigator's opinion)

Triple blinded

Blinding description

The samples did not know the type of implantation of the cardioplegia cannula Caregivers did not know how to insert a cardioplegia cannula The echocardiographer did not know the surgical procedure and the type of cannula implantation

Placebo

Not used

Assignment

Parallel

Other design features

This study is performed on two groups and each group has 36 people. In one group, cardioplegia was injected as antegrade and in the other group as antegrade-retrograde and its effects were compared.

Secondary Ids

empty

Ethics committees**1****Ethics committee****Name of ethics committee**

Isfahan University of Medical Sciences - Committee on Research Ethics

Street address

Hezar jerib st esfahan university of medical sciences

City

Esfahan

Province

Isfahan

Postal code

8174673461

Approval date

2021-09-20, 1400/06/29

Ethics committee reference number

IR.MUI.MED.REC.1400.496

Health conditions studied**1****Description of health condition studied**

Coronary artery disease

ICD-10 code

T82.21

ICD-10 code description

Mechanical complication of coronary artery bypass graft

Primary outcomes**1****Description**

Paradoxical septal motion

Timepoint

Post surgery

Method of measurement

Echocardiography in M mode

Secondary outcomes

empty

Intervention groups**1****Description**

Intervention group: Intervention group: In one group, cardioplegia cannula is inserted by the surgeon in the root of the aorta and the perfusionist injects the cardioplegia through the heart and lung pump. After surgery and before discharge, paradoxical motion of the septum, which is a measure of myocardial protection, are examined by echocardiography.

Category

Diagnosis

2

Description

Intervention group: In the other group, the cardioplegia solution is injected both in the aortic root and through the coronary sinus, which is implanted by a surgeon with a special device, by a perfusionist through a heart and lung pump as in the previous group, and after surgery and before discharge paradoxical motion of The septum is identified by echocardiography.

Category

Diagnosis

Recruitment centers

1

Recruitment center

Name of recruitment center

Chamran hospital

Full name of responsible person

Dr mehran shahzamani

Street address

Salman farsi BlvTchamran hospital

City

Esfahan

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Isfahan

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8174673461

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M.shahzamani@med.mui.ac.ir

Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Esfahan University of Medical Sciences

Full name of responsible person

Research department of Isfahan University of Medical Sciences

Street address

Hezar jerib st, esfahan university of medical science

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Phone

+98 31 3668 0048

Email

M.shahzamani@med.mui.ac.ir

Grant name

Grant code / Reference number

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

Yes

Title of funding source

Esfahan 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

Esfahan University of Medical Sciences

Full name of responsible person

Dr mehran shahzamani

Position

Specialist in cardiovascular surgery

Latest degree

Subspecialist

Other areas of specialty/work

General Surgery

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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**Contact****Name of organization / entity**

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Full name of responsible person

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Sharing plan**Deidentified Individual Participant Data Set (IPD)**

Undecided - It is not yet known if there will be a plan to make this available

Study Protocol

Undecided - It is not yet known if there will be a plan to make this available

Statistical Analysis Plan

Not applicable

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

Undecided - It is not yet known if there will be a plan to make this available

Data Dictionary

Undecided - It is not yet known if there will be a plan to make this available

Title and more details about the data/document

En After finishing the study the data will be available

When the data will become available and for how long

After publishing the article

To whom data/document is available

faculty members

Under which criteria data/document could be used

Contacting the scientist responsible by email causes the data to be used in order to use the data in scientific research such as meta-analysis or secondary analysis.

From where data/document is obtainable

Scientific responsible can provide the study data to academic researchers without the name of individuals. Scientific responsible: Dr.mehran shahzamani. Address: Isfahan. Moshtagh Ave, chanran heart center. postal code: (8174673461). Call number: (+98 31 3670 1227). Mobile phone number: (+98 913 123 1453). Email: m.shahzamani@med.mui.ac.ir

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

Just forwarding email to scientific responsible of this trial is enough. Email address: m.shahzamani@med.mui.ac.ir (Will be answered within a month.)

Comments