

Clinical Trial Protocol

Iranian Registry of Clinical Trials

31 May 2026

The evaluation and comparison of Coronary sinus Inflammatory and ischemic biomarkers level in retrograde-antegrade versus antegrade cardioplegia during cardiopulmonary bypass surgery: A single blinded randomized controlled trial

Protocol summary

Summary

Homogeneous delivery of cardioplegia is an important component of myocardial protection in any patient who undergoes open heart surgery and poorly protected myocardial segments may have decreased function following ischemia. It has been shown that inhomogeneous cardioplegic delivery results in impaired regional and global left ventricular (LV) systolic function, as well as impaired diastolic function. Antegrade delivery of cardioplegia via the aortic root is a common cardioplegic delivery technique while it could result in an inhomogeneous perfusion of myocardium in some kind of cardiac surgery. Retrograde cardioplegia via the coronary sinus is another way of myocardial protection which may provide better protection of myocardium in such patients. Some studies have shown that warm antegrade cardioplegia results in better left ventricular perfusion than warm retrograde cardioplegia while some others are on this supposition that retrograde application of cardioplegia is more advantageous. Because of important affects of cardioplegia on patients outcome, a great need exists to find the differences between retrograde and antegrade cardioplegia with new methods. Therefore, we are on this supposition that measuring ischemic and inflammatory biomarkers in coronary sinus blood sample before, during, and after cardiopulmonary bypass would provide us with more valuable information. 100 patients from Dr.Ghavidel surgery service who meet the inclusion criteria at Rajaei heart center are included in this single blinded randomized clinical trial. All patients are first time candidates for cardiac surgery. They will be randomized into two equal groups with Random number table method of randomization. Procedure: Routin antrograde will be done in control group and routin antrograde-retrograde cardioplegia will be done in treatment group.

Further details are mentioned below. Coronary Sinus Sampling: To determine the effects on myocardial stress, blood samples are taken from the retrograde coronary sinus catheter (before institution of CPB, On removal of aortic cross-clamp, 30 minutes after weaning from CPB) for interleukin (IL)-6, IL-18, and tumor necrosis factor (TNF)-alpha, Na, K, Ca, Lactate, pyruvate and LP (Lactate Pyruvate) ratio, cTnl, sICAM-1, sVCAM-1, Lactate dehydrogenase, high sensitivity C-reactive protein (hsCRP), PH, and HCO₃ levels. Serum samples were also analyzed to measure these biomarkers as well (before institution of CPB, on removal of aortic cross-clamp, 30 minutes, and 12 hours after completion of CPB).

General information

Acronym

IRCT registration information

IRCT registration number: **IRCT201202048860N1**

Registration date: **2013-07-16, 1392/04/25**

Registration timing: **prospective**

Last update:

Update count: **0**

Registration date

2013-07-16, 1392/04/25

Registrant information

Name

Alireza Alizadeh Ghavidel

Name of organization / entity

Rajaei Heart Center

Country

Iran (Islamic Republic of)

Phone

+98 21 2392 2147

Email address

aghavidel@rhc.ac.ir

Recruitment status

Recruitment complete

Funding source

Rajaie Cardiovascular Medical and Research Center

Expected recruitment start date

2014-02-20, 1392/12/01

Expected recruitment end date

2015-02-20, 1393/12/01

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

The evaluation and comparison of Coronary sinus Inflammatory and ischemic biomarkers level in retrograde-antegrade versus antegrade cardioplegia during cardiopulmonary bypass surgery: A single blinded randomized controlled trial

Public title

The evaluation and comparison of Coronary sinus Inflammatory and ischemic biomarkers level in retrograde-antegrade versus antegrade cardioplegia during cardiopulmonary bypass surgery: A single blinded randomized controlled trial

Purpose

Treatment

Inclusion/Exclusion criteria

Inclusion criteria: all patients undergoing cardiopulmonary bypass surgery at one operator service in our institution were prospectively screened for inclusion in the investigation. Consecutive patients with the following characteristics were selected for inclusion in the study: valvular with at least two vessels coronary disease. Exclusion criteria: total respiratory disability; renal failure (Cr > 2); age ≥ 80 years old; history of MI in 4 weeks preoperatively; failure to retrograde catheter insertion; where total respiratory disability is any of: height-corrected FEV1 (1.1-1.4) and DLCO less than 30 percent predicted (Technical revisions to medical criteria for determinations of disability).

Age

From **18 years** old to **80 years** old

Gender

Both

Phase

3

Groups that have been masked

No information

Sample size

Target sample size: **100**

Randomization (investigator's opinion)

Randomized

Randomization description**Blinding (investigator's opinion)**

Single blinded

Blinding description**Placebo**

Not used

Assignment

Parallel

Other design features**Secondary Ids**

empty

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

Tehran University of Medical Sciences

Street address

Junction of Shahid Hemmat and Shahid Chamran expressways

City

Tehran

Postal code**Approval date**

2013-06-22, 1392/04/01

Ethics committee reference number

92-01-14-17083-86435

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

Myocardial Infarction

ICD-10 code

121

ICD-10 code description

myocardial infarction specified as acute or with a stated duration of 4 weeks (28 days) or less from onset

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

Mortality

Timepoint

30-day after surgery

Method of measurement

ID

Secondary outcomes**1****Description**

blood level of IL18 in peripheral blood sample

Timepoint

before institution of CPB, on removal of aortic cross-clamp, 30 minutes, and 12 hours after completion of CPB

Method of measurement

Laboratory kit

2**Description**

blood level of Na in peripheral blood sample

Timepoint

before institution of CPB, on removal of aortic cross-clamp, 30 minutes after completion of CPB

Method of measurement

Laboratory kit

3**Description**

blood level of K in peripheral blood sample

Timepoint

before institution of CPB, on removal of aortic cross-clamp, 30 minutes after completion of CPB

Method of measurement

Laboratory kit

4**Description**

blood level of Ca in peripheral blood sample

Timepoint

before institution of CPB, on removal of aortic cross-clamp, 30 minutes after completion of CPB

Method of measurement

Laboratory kit

5**Description**

blood level of Lactate in peripheral blood sample

Timepoint

before institution of CPB, on removal of aortic cross-clamp, 30 minutes after completion of CPB

Method of measurement

Laboratory kit

6**Description**

blood level of Lactate/Pyruvate in peripheral blood sample

Timepoint

before institution of CPB, on removal of aortic cross-clamp, 30 minutes after completion of CPB

Method of measurement

Laboratory kit

7**Description**

blood level of HSCR in peripheral blood sample

Timepoint

before institution of CPB, on removal of aortic cross-clamp, 30 minutes after completion of CPB

Method of measurement

Laboratory kit

8**Description**blood level of HCO₃ in peripheral blood sample**Timepoint**

before institution of CPB, on removal of aortic cross-clamp, 30 minutes after completion of CPB

Method of measurement

Laboratory kit

9**Description**

blood level of PH in peripheral blood sample

Timepoint

before institution of CPB, on removal of aortic cross-clamp, 30 minutes after completion of CPB

Method of measurement

Laboratory kit

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

Control group: cold, Bloody cardioplegic solution (st. Thomas II based) is applied at an initial volume of 1000 mL in all patients. A second or third shot of 300 to 500 mL is given to patients with restarting electrical heart activity or after 20 minutes of cross-clamp time after the previous application

Category

Treatment - Surgery

2**Description**

Intervention group: the initial dose delivered in the same route and the next cardioplegia will be infused via retrograde catheter 200-300 ml after every distal anastomosis for CABG cases or 300-500 ml every 20 min in other procedures. Antegrade cardioplegia will be re-infused after 40 min for long-time cross clamping time

Category

Treatment - Surgery

Recruitment centers**1****Recruitment center****Name of recruitment center**

Rajaei Heart Center

Full name of responsible person**Street address****City**

Tehran

Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Rajaie cardiovascular medical and research center

Full name of responsible person

Dr. Majid Haghjoo

Street address

Valiasr Ave. Nyayesh Blvd.

City

Tehran

Grant name**Grant code / Reference number****Is the source of funding the same sponsor organization/entity?**

Yes

Title of funding source

Rajaie cardiovascular medical and research center

Proportion provided by this source

100

Public or private sector

empty

Domestic or foreign origin

empty

Category of foreign source of funding

empty

Country of origin**Type of organization providing the funding**

empty

Person responsible for general inquiries

Contact**Name of organization / entity**

Rajaie heart center

Full name of responsible person

Dr. Alireza Alizadeh Ghavidel

Position

Associate Professor

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Web page address

Sharing plan

Deidentified Individual Participant Data Set (IPD)

empty

Study Protocol

empty

Statistical Analysis Plan

empty

Informed Consent Form

empty

Clinical Study Report

empty

Analytic Code

empty

Data Dictionary

empty