

# 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 HCO<sub>3</sub> 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 HCO<sub>3</sub> 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

**Other areas of specialty/work**

**Street address**

Valiasr Ave, Nyayesh Blvd

**City**

Tehran

**Postal code**

**Phone**

+98 21 2392 2147

**Fax**

**Email**

aghavidel@rhc.ac.ir

**Web page address**

### Person responsible for scientific inquiries

**Contact**

**Name of organization / entity**

Rajaie Heart Center

**Full name of responsible person**

Dr. Alireza Alizadeh Ghavidel

**Position**

Associate Professor

**Other areas of specialty/work**

**Street address**

Valiasr Ave, Nyayesh Blvd.

**City**

Tehran

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**Phone**

+98 21 2392 2147

**Fax**

**Email**

aghavidel@rhc.ac.ir

**Web page address**

### Person responsible for updating data

**Contact**

**Name of organization / entity**

Rajaei Heart Center

**Full name of responsible person**

Dr. Alireza Alizadeh Ghavidel

**Position**

Associate Professor

**Other areas of specialty/work**

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### 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*