

# Clinical Trial Protocol

## Iranian Registry of Clinical Trials

27 Jun 2026

### Comparisson of the Efficacy of Ringer's Lactate Serum as a Base Solution in Modified Del Nido Cardioplegia with Standard Del Nido Cardioplegia on Myocardial Damage Markers and Clinical Outcomes in Patients Undergoing Coronary Artery Bypass Graft

#### Protocol summary

##### Study aim

Comparisson of the Efficacy of Ringer's Lactate Serum as a Base Solution in Modified Del Nido Cardioplegia with Standard Del Nido Cardioplegia on Myocardial Damage Markers and Clinical Outcomes in Patients Undergoing Coronary Artery Bypass Graft

##### Design

Randomized, single-blinded controlled trial, with parallel groups (allocation ratio 1:1).

##### Settings and conduct

This study is performed on patients who are candidates for coronary artery bypass surgery in Imam Hossein hospital (Tehran, Iran) in 1401. Eligible patients are divided into two groups (A and B) using a table of random numbers. In groups A and B, Ringer's lactate and plasmalite A solution are used for cardioplegia, respectively. Then, the markers of myocardial damage and the clinical outcomes of patients after surgery and at the admission to the intensive care unit are evaluated. In this single-blinded study, the patients are unaware of the allocation of individuals to the groups.

##### Participants/Inclusion and exclusion criteria

Inclusion criteria are: Candidate patients for coronary artery bypass graft, Candidate patients for 3 to 4 vascular grafts, Age between 18 and 75 years, Written informed consent to participate in the study, An ejection fraction higher than 35% before surgery, and Lack of multi-organ failure before surgery. Exclusion criteria are: Re-operation and Proven infection or inflammation within the last month

##### Intervention groups

In this study, Ringer's lactate solution is used to cardioplegia in group A (modified Del Nino). Also, in group B, plasmalit A solution is used to cardioplegia (Del Nino standard). Cardioplegic solution is a solution that is used to protect the myocardium during surgery and

during the period when the heart is deprived of blood circulation.

##### Main outcome variables

Clinical outcomes; Myocardial damage markers

#### General information

##### Reason for update

##### Acronym

##### IRCT registration information

IRCT registration number: **IRCT20210825052284N1**

Registration date: **2022-09-28, 1401/07/06**

Registration timing: **prospective**

Last update: **2022-09-28, 1401/07/06**

Update count: **0**

##### Registration date

2022-09-28, 1401/07/06

##### Registrant information

##### Name

salimeh janghorban

##### Name of organization / entity

##### Country

Iran (Islamic Republic of)

##### Phone

+98 21 7343 0000

##### Email address

sali.cardiology@yahoo.com

##### Recruitment status

**Recruitment complete**

##### Funding source

##### Expected recruitment start date

2022-10-23, 1401/08/01

##### Expected recruitment end date

2023-01-21, 1401/11/01

**Actual recruitment start date**  
empty

**Actual recruitment end date**  
empty

**Trial completion date**  
empty

**Scientific title**  
Comparisson of the Efficacy of Ringer's Lactate Serum as a Base Solution in Modified Del Nido Cardioplegia with Standard Del Nido Cardioplegia on Myocardial Damage Markers and Clinical Outcomes in Patients Undergoing Coronary Artery Bypass Graft

**Public title**  
Comparisson of the Efficacy of Ringer's Lactate Serum as a Base Solution in Modified Del Nido Cardioplegia with Standard Del Nido Cardioplegia on the Outcomes in Patients Undergoing Coronary Artery Bypass Graft

**Purpose**  
Treatment

**Inclusion/Exclusion criteria**  
**Inclusion criteria:**  
Candidate patients for coronary artery bypass graft  
Candidate patients for 3 to 4 vascular grafts  
Age between 18 and 75 years  
Written informed consent to participate in the study  
An ejection fraction higher than 35% before surgery  
Lack of multi-organ failure before surgery  
**Exclusion criteria:**  
Re-operation  
Proven infection or inflammation within the last month

**Age**  
From **18 years** old to **75 years** old

**Gender**  
Both

**Phase**  
N/A

**Groups that have been masked**  

- Participant

**Sample size**  
Target sample size: **60**

**Randomization (investigator's opinion)**  
Randomized

**Randomization description**  
The randomization method is a simple randomization that is done in the form of individual random units. The tool used to do this is a random numbers table. The method of constructing a random sequence is that first the researcher selects one of the numbers with his eyes closed and then moves in the right direction. Odd numbers are considered for intervention and even numbers are for control. Random concealment is also performed using sequentially numbered sealed opaque envelopes (SNOSE).

**Blinding (investigator's opinion)**  
Single blinded

**Blinding description**  
In this single-blinded study, patients who are candidates for coronary artery bypass grafting are blind to the group

assignment. Others, including treating physician, methodologist, statistics specialist, nurses, authors of manuscript, and study designers, will be aware of the classification of patients into the two groups.

**Placebo**  
Not used

**Assignment**  
Parallel

**Other design features**

**Secondary Ids**  
empty

## Ethics committees

### 1

#### Ethics committee

##### Name of ethics committee

Research Ethics Committees of School of Medicine, Shahid Beheshti University of Medical Sciences

##### Street address

School of medicine of Shahid Beheshti University of medical sciences, Koodakyar Ave., Daneshjoo Blvd., Yaman St., Chamran highway.

##### City

Tehran

##### Province

Tehran

##### Postal code

1985717443

#### Approval date

2022-04-12, 1401/01/23

#### Ethics committee reference number

IR.SBMU.MSP.REC.1401.023

## Health conditions studied

### 1

#### Description of health condition studied

Coronary artery bypass graft

#### ICD-10 code

T82.2

#### ICD-10 code description

Mechanical complication of coronary artery bypass graft and biological heart valve graft

## Primary outcomes

### 1

#### Description

Ejection fraction

#### Timepoint

Before surgery, after surgery, and 24 hours after admission to the intensive care unit

#### Method of measurement

Echocardiography

## 2

### **Description**

Duration of mechanical ventilation

### **Timepoint**

Daily after surgery

### **Method of measurement**

Medical record of the patients

## 3

### **Description**

Arrhythmia incidence

### **Timepoint**

Daily after surgery

### **Method of measurement**

Electrocardiogram device and cardiologist's interpretation

## 4

### **Description**

Inotrope administration

### **Timepoint**

Daily after surgery

### **Method of measurement**

Medical record of the patients

## **Secondary outcomes**

## 1

### **Description**

Troponin level

### **Timepoint**

Before surgery, after surgery, and 24 hours after admission to the intensive care unit

### **Method of measurement**

Laboratory report

## 2

### **Description**

Lactate dehydrogenase level

### **Timepoint**

Before surgery, after surgery, and 24 hours after admission to the intensive care unit

### **Method of measurement**

Laboratory report

## **Intervention groups**

## 1

### **Description**

Intervention group A: In this study, Ringer's lactate solution is used to cardioplegia in group A (modified Del Nino).

### **Category**

Treatment - Drugs

## 2

### **Description**

Intervention group B: In this study, plasmalit A solution is used to cardioplegia in group B (Del Nino standard).

### **Category**

Treatment - Drugs

## **Recruitment centers**

## 1

### **Recruitment center**

#### **Name of recruitment center**

Imam Hossein Hospital

#### **Full name of responsible person**

Salimeh Janghorban

#### **Street address**

Imam Hossein Hospital, Shahid Madani St., Imam Ali Highway, Tehran

#### **City**

Tehran

#### **Province**

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#### **Postal code**

1617763141

#### **Phone**

+98 21 7343 3000

#### **Email**

info@ehmc.ir

## **Sponsors / Funding sources**

## 1

### **Sponsor**

#### **Name of organization / entity**

Shahid Beheshti University of Medical Sciences

#### **Full name of responsible person**

Dr. Afshin Zarghi

#### **Street address**

Shahid Beheshti University of Medical Sciences, No. 2, Arabi St., Yemen St., Chamran Highway, Tehran, Iran

#### **City**

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#### **Province**

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1983969411

#### **Phone**

+98 21 2243 9780

#### **Email**

Mpajouhesh@sbmu.ac.ir

### **Grant name**

### **Grant code / Reference number**

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

Yes

### **Title of funding source**

Shahid Beheshti 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

Tehran

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1615614361

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Sali.cardiology@yahoo.com

**Person responsible for general inquiries****Contact****Name of organization / entity**

Shahid Beheshti University of Medical Sciences

**Full name of responsible person**

Salimeh Janghorban

**Position**

Resident

**Latest degree**

Medical doctor

**Other areas of specialty/work**

Cardiology

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**Position**

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**Latest degree**

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**Other areas of specialty/work**

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**Street address**

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**City**

Tehran

**Province****Person responsible for updating data****Contact****Name of organization / entity**

Shahid Beheshti University of Medical Sciences

**Full name of responsible person**

Salimeh Janghorban

**Position**

Resident

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+98 21 7757 9045

**Email**

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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**

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

**Informed Consent Form**

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

**Clinical Study Report**

Undecided - It is not yet known if there will be 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