

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)

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+98 21 7343 0000

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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.

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Province

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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

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

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Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Shahid Beheshti University of Medical Sciences

Full name of responsible person

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

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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

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

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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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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