

Clinical Trial Protocol

Iranian Registry of Clinical Trials

11 Sep 2026

Comparison of routine del Nido cardioplegia vs two types of modified del Nido cardioplegias for myocardial protection among patients undergoing coronary artery bypass grafting (CABG) surgeries

Protocol summary

Study aim

To determine the effect of routine del Nido and modified del Nido cardioplegia over myocardial protection on the basis of cardio markers

Design

A randomized, double-blinded, controlled trial with parallel groups

Settings and conduct

A randomized, double-blinded, controlled trial with parallel groups. faghihi hospital

Participants/Inclusion and exclusion criteria

Inclusion Criteria: Patients of age more than 18-year-old with minimum 30 % ejection fraction and triple vessel coronary artery disease referred for elective isolated coronary artery bypass grafting (CABG) surgery needing cardiopulmonary bypass will be enrolled.

Intervention groups

Patients undergoing elective myocardial revascularization surgery (CABG) will be randomized to receive cardioplegic solutions del Nido (Normal Saline as the base solution), modified del Nido (using lactated Ringer's as the base solution) or (using Plain Ringer's as the base solution) during CPB. They will be followed up for evaluating the effectiveness of the treatments initially proposed.

Main outcome variables

Primary Outcomes: Myocardial protection between routine and modified del Nido Cardioplegia solution via CK-MB, Troponin T, Troponin I, and lactate just after anesthesia induction and the immediate postoperative period 2 hours as well as 12 hours and 24 hours after the CPB. Secondary Outcomes: The secondary outcomes include: Incidence of post aortic clamp off ventricular fibrillation requiring electrical defibrillation (DC Shock), the total volume of cardioplegia and number of doses, cardiopulmonary bypass time, aortic cross-clamp time, and mortality, incidence of postoperative atrial fibrillation

(AF) and Atrial flutter (AFL), mechanical ventilation support time, total ICU stay, and mortality.

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20230719058845N1**

Registration date: **2023-08-21, 1402/05/30**

Registration timing: **prospective**

Last update: **2023-08-21, 1402/05/30**

Update count: **0**

Registration date

2023-08-21, 1402/05/30

Registrant information

Name

Mohammad Ghazinour

Name of organization / entity

Country

Iran (Islamic Republic of)

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+98 71 3647 4270

Email address

ghazinour@sums.ac.ir

Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2023-08-27, 1402/06/05

Expected recruitment end date

2023-11-26, 1402/09/05

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date
empty

Scientific title
Comparison of routine del Nido cardioplegia vs two types of modified del Nido cardioplegias for myocardial protection among patients undergoing coronary artery bypass grafting (CABG) surgeries

Public title
Comparison of routine del Nido cardioplegia vs two types of modified del Nido cardioplegias for myocardial protection among patients undergoing coronary artery bypass grafting (CABG) surgeries

Purpose
Treatment

Inclusion/Exclusion criteria
Inclusion criteria:
 Patients of age more than 18-year-old with minimum 30% ejection fraction and triple vessel coronary artery disease referred for elective isolated coronary artery bypass grafting (CABG) surgery needing cardiopulmonary bypass will be included .
Exclusion criteria:
 Patients with a history of previous cardiac surgery, chronic renal disease (had a previous medical diagnosis or serum creatinine greater than 1.5 mg/dL), perioperative pregnancy, an implanted pacemaker or intracardiac defibrillator, patient requiring preoperative mechanical support, severe psychiatric illness, and inability or unwillingness to give informed consent for participation will be excluded.

Age
From **18 years** old

Gender
Both

Phase
4

Groups that have been masked

- Participant
- Care provider
- Investigator
- Outcome assessor
- Data analyser
- Data and Safety Monitoring Board

Sample size
Target sample size: **120**

Randomization (investigator's opinion)
Randomized

Randomization description
A total of 120 patients will be divided into three groups with 40 individuals in each group. This will be done randomly using block randomization, with a blocked randomization list generated from www.sealedenvelope.com in blocks of 6 (6*20=120).

Blinding (investigator's opinion)
Double blinded

Blinding description
To ensure confidentiality, the treatment allocation will be concealed from study personnel, outcome assessors, and

participants. This will be achieved through the use of sequentially numbered sealed opaque envelopes. On the day of the surgery, the perfusionist will receive a sealed envelope with instructions on the cardioplegic solution to prepare and administer according to its specificities before administering anesthesia. To avoid any biases, the surgical team, patients, anesthetists, nurses, and laboratory staff will be blinded to the type of intervention used. After the surgery, the patients will be transferred to the ICU and monitored by a team with post-operative expertise in the specialty, according to standard institutional protocols. The team will also be blinded to the type of cardioplegia used during the surgery. The patients will then be transferred to the postoperative cardiology unit, where they will be managed until hospital discharge by the responsible team, following standard protocols, and also blinded to the type of intervention. The lead investigator, who will identify the outcomes and perform the statistical analyses, will also remain blind to the allocation of patients regarding the type of intervention. During the adjudication process, all researchers will be kept unaware of the patient's allocation to different interventions. The data obtained from the adjudication will be utilized in the final analysis of safety and effectiveness. All data will be evaluated by two authors independently, with quality control on data entry to verify amplitude and consistency.

Placebo

Not used

Assignment

Parallel

Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee

research ethics committees school of medicine _shiraz university of medical sciences

Street address

Zand Street, Shiraz University of Medical Sciences

City

shiraz

Province

Fars

Postal code

71936-13311

Approval date

2023-02-01, 1401/11/12

Ethics committee reference number

IR.SUMS.MED.REC.1401.534

Health conditions studied

1

Description of health condition studied

Coronary Artery Disease

ICD-10 code

For morbid

ICD-10 code description

For morbidity, duration as used in categories I21, I22, I24 and I25 refer to the interval elapsing between onset of the ischaemic episode and admission to care. For mortality, duration refers to the interval elapsing between onset and death.

Primary outcomes

1

Description

Ventricular fibrillation

Timepoint

After removing the aorta clamp

Method of measurement

Electrocardiogram

2

Description

Troponin and CK-MB Level

Timepoint

Immediately after the operation and 6 hours after the operation

Method of measurement

Lab Data

Secondary outcomes

1

Description

ICU stay,

Timepoint

The days after the operation

Method of measurement

Number of days of hospitalization

Intervention groups

1

Description

Intervention group:

Category

Treatment - Surgery

Recruitment centers

1

Recruitment center

Name of recruitment center

Shahid Faqihi Hospital, Shiraz

Full name of responsible person

Dr. Mohammad Ghazi Noor

Street address

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Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Shiraz University of Medical Sciences

Full name of responsible person

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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

Shiraz University of Medical Sciences

Proportion provided by this source

70

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

Shiraz University of Medical Sciences

Full name of responsible person

Dr. Mohammad Ghazi Noor

Position

Cardiac surgeon
Latest degree
Subspecialist
Other areas of specialty/work
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Person responsible for updating data

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Sharing plan

Deidentified Individual Participant Data Set (IPD)

Yes - There is 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

Title and more details about the data/document

pdf

When the data will become available and for how long

One Month

To whom data/document is available

Students and interested people

Under which criteria data/document could be used

Use in the process of treating patients

From where data/document is obtainable

To the university library and the person responsible for the study

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

Refer to the university library or refer to the respondent of the study

Comments