Clinical Trial Protocol
Iranian Registry of Clinical Trials

22 Nov 2026

Comparison of routine del Nido cardioplegia vs two types of modified del Nido cardioplegias for myocardialprotection 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 ۱۸-year-old with minimum ۳۰ % 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

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Iran (Islamic Republic of)

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+98 71 3647 4270

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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 myocardialprotection 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 ۱۸-year-old with minimum ۳۰ % 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 committes school of medicine _shiraz uiversity 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
zand street
City
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71936-13311
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Sponsors / Funding sources

1

Sponsor
Name of organization / entity
Shiraz University of Medical Sciences
Full name of responsible person
Dr. Mohammad Ghazi Noor
Street address
zand street
City
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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
Cardiology

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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