Clinical Trial Protocol
Iranian Registry of Clinical Trials

07 Jun 2026

Evaluating the effect of Del Nido cardioplegia solution containing Vitamin C on perioperative clinical outcomes and laboratory criteria of CABG patients

Protocol summary

Study aim

Main goal: Evaluating and study the effect of Del Nido cardioplegia solution containing Vitamin C on perioperative clinical outcomes and laboratory criteria of CABG patients

Design

Clinical trial with control group, with parallel groups, Randomized, designed for 70 patients, Block randomization with size 6 and Individual randomization unit (using https://www.sealedenvelope.com/simple-randomiser/v1/lists;CREATE A RANDOMISATION LIST)

Settings and conduct

Rajee Heart center For gathering data in this trial consent form will be taken from suitable candidates before entering the operation room and then patients in order of acceptance in OR using described randomization(using https://www.sealedenvelope.com/simple-randomiser/v1/lists;CREATE A RANDOMISATION LIST) ; randomized into vitamin C group (35 patients) and control group (35 patients) and eventually 70 patients will participate in this trial.

Participants/Inclusion and exclusion criteria

Inclusion criteria: 1-Tendency to participate 2-Consent 3-Age between 30 to 70 4-LVEF more than 30% Exclusion criteria: 1-Above normal range cardiac enzymes 2-History of sternotomy and previous cardiac surgeries 3-History of Liver, Kidney, Pulmonary diseases 4-Valve problems that requires concurrent surgery 5-Having pacemaker 6-Pregnancy 7-History of allergic reaction to Vitamin C 8-G6PD deficiency

Intervention groups

Intervention group: adding 3 gram of injectable Vitamin C (6 VITAMIN C DP 500MG/5ML AMP) to Del Nido cardioplegia solution (1 L Plasma-Lyte A base solution to which the following are added: Mannitol 20%, 16.3 mL Magnesium sulfate 50%, 4 mL Sodium bicarbonate 8.4%, 13 mL Potassium chloride (2 mEq/mL), 13 mL Lidocaine 1%, 13 mL) Control group: Inject Del Nido cardioplegia solution

Main outcome variables

Troponin CK-MB BUN Cr LFT

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20220716055477N1**
Registration date: **2022-08-15, 1401/05/24**
Registration timing: **prospective**

Last update: **2022-08-15, 1401/05/24**
Update count: **0**

Registration date

2022-08-15, 1401/05/24

Registrant information

Name
Mohammadhadi Mozayan
Name of organization / entity
Rajaee Heart Center
Country
Iran (Islamic Republic of)
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+98 71 3242 4118
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Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2022-09-06, 1401/06/15

Expected recruitment end date
2023-03-06, 1401/12/15
Actual recruitment start date
empty
Actual recruitment end date
empty
Trial completion date
empty

Scientific title
Evaluating the effect of Del Nido cardioplegia solution containing Vitamin C on perioperative clinical outcomes and laboratory criteria of CABG patients

Public title
Evaluating the effect of Del Nido cardioplegia solution containing Vitamin C on perioperative clinical outcomes and laboratory criteria of CABG patients
Purpose
Treatment
Inclusion/Exclusion criteria
Inclusion criteria:
Tendency to participate Consent Age between 30 to 70 LVEF more than 30%
Exclusion criteria:
Above normal range cardiac enzymes History of sternotomy and previous cardiac surgeries History of Liver, Kidney, Pulmonary diseases Valve problems that requires concurrent surgery Having pacemaker Pregnancy History of allergic reaction to Vitamin C G6PD deficiency
Age
From **30 years** old to **70 years** old
Gender
Both

Phase
N/A
Groups that have been masked
No information
Sample size
Target sample size: **70**
Randomization (investigator's opinion)
Randomized
Randomization description
Using block randomization with size 6 and Individual randomization unit (using https://www.sealedenvelope.com/simple-randomiser/v1/lists;CREATE A RANDOMISATION LIST) a list with 72 numbers that accidentally divided into two different groups was made. First group consider as intervention group and second group consider as control groups. For gathering data in this trial consent form will be taken from suitable candidates before entering the operation room and then patients in order of acceptance in OR (with completely interchangeable orders) based on created numbers that described earlier will be divided into vitamin C group (35 patients) and control group (35 patients) and eventually 70 patients will participate in this trial.
Blinding (investigator's opinion)
Not blinded
Blinding description
Placebo
Not used
Assignment
Parallel
Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee
Name of ethics committee
Ethics committee of Rajaee Heart Center
Street address
Rajaee Heart Center, Next to Mellat Park, Valiasr street
City
Tehran
Province
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Postal code
1995614331
Approval date
2022-07-16, 1401/04/25
Ethics committee reference number
IR.RHC.REC.1401.021

Health conditions studied

1

Description of health condition studied
Coronary Artery Bypass Graft Surgery
ICD-10 code
I25.1
ICD-10 code description
Atherosclerotic heart disease of native coronary artery

Primary outcomes

1

Description
Troponin I is a cardiac and skeletal muscle protein family. It is a part of the troponin protein complex, where it binds to actin in thin myofilaments to hold the actin-tropomyosin complex in place. Troponin I prevents myosin from binding to actin in relaxed muscle. When calcium binds to the troponin C, it causes conformational changes which lead to dislocation of troponin I. Afterwards, tropomyosin leaves the binding site for myosin on actin leading to contraction of muscle. The letter I is given due to its inhibitory character. It is a useful marker in the laboratory diagnosis of heart attack. It occurs in different plasma concentration but the same circumstances as troponin T - either test can be performed for confirmation of cardiac muscle damage and laboratories usually offer one test or the other

Timepoint
pre-operation, upon admission to the Intensive Care Unit, and 24 hours later
Method of measurement
Using accurate laboratory kits

2

Description
Creatine kinase-MB (CK-MB) is a form of an enzyme found primarily in heart muscle cells. This test measures CK-MB in the blood.CK-MB is one of three forms (isoenzymes) of the enzyme creatine kinase (CK). These isoenzymes include :CK-MM (found in skeletal muscles and the heart)CK-MB (found mostly in the heart, but small amounts found in skeletal muscles)CK-BB (found mostly in the brain and smooth muscle, such as the intestines and uterus)CK is released from muscle cells and is detectable in the blood whenever there is muscle damage. The small amount of CK that is normally in the blood is primarily CK-MM. CK-BB almost never gets into the blood, and CK-MB will typically only be present in significant amounts when the heart is damaged. A CK test measures the total level but does not distinguish between the three isoenzymes. When there is an increased amount of CK present in the blood, the CK-MB test can be used to determine whether it is due to heart damage or is more likely to be related to skeletal muscle injury.
Timepoint
pre-operation, upon admission to the Intensive Care Unit, and 24 hours later
Method of measurement
Using accurate laboratory kits

Secondary outcomes

1

Description
Blood urea nitrogen (BUN) is a medical test that measures the amount of urea nitrogen found in blood. The liver produces urea in the urea cycle as a waste product of the digestion of protein. Normal human adult blood should contain 6 to 20 mg/dL (2.1 to 7.1 mmol/L) of urea nitrogen. Individual laboratories will have different reference ranges as the assay used can vary between laboratories. The test is used to detect renal problems.
Timepoint
pre-operation, upon admission to the Intensive Care Unit, 24 and 48 hours later
Method of measurement
Using accurate laboratory kits

2

Description
Serum creatinine (a blood measurement) is an important indicator of kidney health because it is an easily measured byproduct of muscle metabolism that is excreted unchanged by the kidneys. Creatinine itself is produced via a biological system involving creatine, phosphocreatine (also known as creatine phosphate), and adenosine triphosphate (ATP, the body's immediate energy supply).
Timepoint
pre-operation, upon admission to the Intensive Care Unit, 24 and 48 hours later
Method of measurement
Using accurate laboratory kits

3

Description
Liver function tests (LFTs or LFs), also referred to as a hepatic panel, are groups of blood tests that provide information about the state of a patient's liver. The liver transaminases aspartate transaminase (AST or SGOT) and alanine transaminase (ALT or SGPT) are useful biomarkers of liver injury in a patient with some degree of intact liver function.
Timepoint
pre-operation, upon admission to the Intensive Care Unit, 24 and 48 hours later
Method of measurement
Using accurate laboratory kits

Intervention groups

1

Description
Intervention group: adding 3 gram of injectable Vitamin C (6 VITAMIN C DP 500MG/5ML AMP) to Del Nido cardioplegia solution (1 L Plasma-Lyte A base solution to which the following are added: Mannitol 20%, 16.3 mL Magnesium sulfate 50%, 4 mL Sodium bicarbonate 8.4%, 13 mL Potassium chloride (2 mEq/mL), 13 mL Lidocaine 1%, 13 mL)
Category
Treatment - Drugs

2

Description
Control group: Inject Del Nido cardioplegia solution (1 L Plasma-Lyte A base solution to which the following are added: Mannitol 20%, 16.3 mL Magnesium sulfate 50%, 4 mL Sodium bicarbonate 8.4%, 13 mL Potassium chloride (2 mEq/mL), 13 mL Lidocaine 1%, 13 mL)
Category
Treatment - Drugs

Recruitment centers

1

Recruitment center
Name of recruitment center
Rajee Heart center
Full name of responsible person
Mohammadhadi Mozayan
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Sponsors / Funding sources

1

Sponsor

Name of organization / entity
Rajaee Heart Center

Full name of responsible person
Dr.Majid Maleki

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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
Rajaee Heart Center

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

Person responsible for general inquiries

Contact

Name of organization / entity
Rajaee Heart Center

Full name of responsible person
Mohammadhadi Mozayan

Position
Master of Science Student

Latest degree
Bachelor

Other areas of specialty/work
Nursery

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Person responsible for scientific inquiries

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Position
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Latest degree
Bachelor

Other areas of specialty/work
Nursery

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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
Yes - There is a plan to make this available
Statistical Analysis Plan
Yes - There is 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
Yes - There is a plan to make this available
Analytic Code
Yes - There is 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
Evaluating the effect of Del Nido cardioplegia solution containing Vitamin C on perioperative clinical outcomes and laboratory criteria of CABG patients
When the data will become available and for how long
The access period starts 6 months after the results are published
To whom data/document is available
Researchers working in academic and scientific institutions
Under which criteria data/document could be used
Science production and teaching methodology
From where data/document is obtainable
Dr. Farshad Jalili Shahandashti Jalilishfarshad@gmail.com
What processes are involved for a request to access data/document
Valid request via academic email
Comments