

# 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

Rajae Heart Center

##### Country

Iran (Islamic Republic of)

##### Phone

+98 71 3242 4118

##### Email address

hadimozayan@rhc.ac.ir

##### 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 Rajae Heart Center

**Street address**

Rajae Heart Center, Next to Mellat Park, Valiasr street

**City**

Tehran

**Province**

Tehran

**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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Rajae Heart Center, Next to Mellat Park, Valiasr street

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hadimozayan@gmail.com

## Sponsors / Funding sources

### 1

**Sponsor**

**Name of organization / entity**

Rajae Heart Center

**Full name of responsible person**

Dr.Majid Maleki

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**Email**

hadimozayan@gmail.com

**Grant name**

**Grant code / Reference number**

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

Yes

**Title of funding source**

Rajae 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**

Rajae 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

**Contact**

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Rajae Heart Center

**Full name of responsible person**

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**Position**

Master of Science Student

**Latest degree**

Bachelor

**Other areas of specialty/work**

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## Person responsible for updating data

**Contact**

**Name of organization / entity**

Rajae Heart Center

**Full name of responsible person**

Mohammadhadi Mozayan

**Position**

Master of Science Student

**Latest degree**

Bachelor

**Other areas of specialty/work**

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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**