Clinical Trial Protocol
Iranian Registry of Clinical Trials

22 Jul 2026

Comparison the myocardial protection effect of modified Buck Berg Cardioplegia with modified Del Nido in adult patients under Mitral valve surgery

Protocol summary

Study aim
Evaluation of the myocardial protective effects of two models of cardioplegia solution, Buck Berg and Del Nido

Design
A randomized, controlled, two-blind, paralelled clinical trial

Settings and conduct
This study was performed in Rajaie cardiovascular center on patients undergoing bypass for mitral valve surgery and to compare the protective effects on cardiac muscle with two types of cardioplegia solutions.

Participants/Inclusion and exclusion criteria
• Elective mitral valve replacement or repair surgery for the first time • Cardiopulmonary bypass with cardiac arrest • Age 22 - 72 years • EF equal or more than 40% preoperative • pulmonary artery pressure less than or equal to 50 mmHg preoperatively Exclusion criteria • Need for medication support (receiving inotropes before starting cardiac surgery) • Having ICD

Intervention groups
Patients were studied in two groups of tests including Del Nido Cardioplegia and control including Buckle Berg Cardioplegia

Main outcome variables
1- The time and rhythm of getting heart arrest 2. Time and rhythm of returning cardiac activity 3. Need for pacemaker and defibrillation 4- Inotropic need for getting off bypass and in ICU 5. EF cardiac output rate

General information

Reason for update

Acronym

IRCT registration information
IRCT registration number: **IRCT20191024045227N1**
Registration date: **2020-04-21, 1399/02/02**
Registration timing: **retrospective**
Last update: **2020-04-21, 1399/02/02**
Update count: **0**

Registration date
2020-04-21, 1399/02/02

Registrant information
Name
Amene Ghanbari
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Recruitment status
Recruitment complete

Funding source

Expected recruitment start date
2018-04-21, 1397/02/01

Expected recruitment end date
2018-08-23, 1397/06/01

Actual recruitment start date
2018-04-21, 1397/02/01

Actual recruitment end date
2018-12-28, 1397/10/07

Trial completion date
2018-12-28, 1397/10/07

Scientific title
Comparison the myocardial protection effect of modified Buck Berg Cardioplegia with modified Del Nido in adult patients under Mitral valve surgery

Public title
Myocardial protection in cardiac surgery

Purpose
Treatment

Inclusion/Exclusion criteria

Inclusion criteria:

• Patients undergoing elective (first) mitral valve replacement or repair surgery for the first time • Patients with cardiopulmonary bypass who need cardiac arrest (cross-clamp and cardioplegia injection) • Age 22 - 72 years • EF equal or more than 40% preoperative • CPB time more than 60 min and less than 120 min • Having elective surgical consent • pulmonary artery pressure less than or equal to 50 mmHg preoperatively

Exclusion criteria:

• Previous Cardiac Surgery (Recurrent Patients) • EF less than 40% • pulmonary artery pressure more than 50 mmhg • Ventricular hypertrophy • Need for medication support (receiving inotropes before starting cardiac surgery) • Having a pacemaker or implantable cardioverter/defibrillator (ICD)

Age

From **22 years** old to **72 years** old

Gender

Both

Phase

3

Groups that have been masked

- Participant
- Care provider
- Outcome assessor

Sample size

Target sample size: **74**

Actual sample size reached: **75**

Randomization (investigator's opinion)

Randomized

Randomization description

Randomization was performed by Random Allocation Software. Samples were divided into two groups according to Balanced Block Randomization (Blood and Del Nido cardioplegia). Patients were randomly assigned to either Blood or Del Nido Cardioplegia according to the order of inclusion and selection, and cardioplegia was injected according to the order of each group.

Blinding (investigator's opinion)

Double blinded

Blinding description

Due to the nature of the intervention and the difference in blood and cardioplegia proportions in the two types of blood (Buck Berg) and Del Nidoo cardioplegic solutions, it was not possible to blind the study to the perfusionist and surgeon. According to the definitions given for the type of cardioplegia solution used in the two groups of patients, it was noted that in Blood cardioplegia the proportion of blood to the cardioplegia solution is 4 to 1 (four times more blood is injected per dose) than in the Dil Nido solution. Conversely, this value is 1 to 4 (one quarter of blood solution is added per injection). This difference in the proportion of blood and cardioplegia and the difference in the interval required for repeated infusion of the solution reveals it to the perfusionist and surgeon.But other members of the ICU surgical team and carers did not know the type of cardioplegia used. (two sided blind).to 1 (four times more blood is injected per dose) than in the Dil Nido solution. Conversely, this value is 1 to 4 (one quarter of blood solution is added per injection). This difference in the proportion of blood and cardioplegia and the difference in the interval required for repeated infusion of the solution reveals it to the perfusionist and surgeon.But other members of the ICU surgical team and carers did not know the type of cardioplegia used. (two sided blind).

Placebo

Not used

Assignment

Parallel

Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee

Ethics committee of Mashhad medical university

Street address

Mashhad University of medical sciences, Vakil Abadblvd

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Province

Razavi Khorasan

Postal code

9177948564

Approval date

2018-11-24, 1397/09/03

Ethics committee reference number

IR.MUMS.MEDICAL.REC.1398.627

Health conditions studied

1

Description of health condition studied

Cardiopulmonary bypass

ICD-10 code

I34.9

ICD-10 code description

Nonrheumatic mitral valve disorder, unspecified

Primary outcomes

1

Description

- Myocardial function

Timepoint

1- pre operation 2 - post cardiopulmonary bypass 3 - post ICU 4 - post ICU

Method of measurement

1- Echocardiography

2

Description
- ICU stay

Timepoint
Time to transfer the patient from the ICU to the post-ICU care unit

Method of measurement
Day of ICU stay

Secondary outcomes

empty

Intervention groups

1

Description
Intervention group: Intervention group: In the intervention group, the patient’s heart was stopped for cardiac surgery procedure with Dell Nido cardioplegia solution. In the treatment of cardiovascular disease surgical interventions are sometimes required. In order to enter the heart cavity and perform valve surgery, the heart needs to be stopped and free of blood. To do this, the patient is placed on an out-of-body circulatory system called cardiopulmonary bypass to replace the heart and lung function with an external system and protect other organs with it. In this way, blood is temporarily mimicked outside the patient's cardiovascular system, and the heart, lungs and sometimes kidneys are temporarily replaced by an alternative system. In patients undergoing bypass, a solution called cardioplegia is used to stop and make the heart bloodless. In this procedure, which is very complex and sensitive, it is necessary to consider many considerations so that after the end of the period of bloodlessness and stopping, the heart can begin to function with the proper energy and power. Certainly, patient health is directly linked to heart health and heart health as well as to the best ways to protect it against the effects of anemia and stoppage, re-circulation and resumption of activity.

Category
Treatment - Surgery

2

Description
Control group: In the control group, the patient’s heart was stopped for cardiac surgery procedure with Buck berg cardioplegia solution.In the treatment of cardiovascular disease surgical interventions are sometimes required. In order to enter the heart cavity and perform valve surgery, the heart needs to be stopped and free of blood. To do this, the patient is placed on an out-of-body circulatory system called cardiopulmonary bypass to replace the heart and lung function with an external system and protect other organs with it. In this way, blood is temporarily mimicked outside the patient's cardiovascular system, and the heart, lungs and sometimes kidneys are temporarily replaced by an alternative system. In patients undergoing bypass, a solution called cardioplegia is used to stop and make the heart bloodless. In this procedure, which is very complex and sensitive, it is necessary to consider many considerations so that after the end of the period of bloodlessness and stopping, the heart can begin to function with the proper energy and power. Certainly, patient health is directly linked to heart health and heart health as well as to the best ways to protect it against the effects of anemia and stoppage, re-circulation and resumption of activity.

Category
Treatment - Surgery

Recruitment centers

1

Recruitment center

Name of recruitment center
Rajaie cardiovascular medical - treatment and research center

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Sponsors / Funding sources

1

Sponsor

Name of organization / entity
Iran 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
Iran 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

Person responsible for general inquiries

Contact
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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
Yes - There is 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
Yes - There is a plan to make this available
Title and more details about the data/document
All information about the study procedure and its implications are available.
When the data will become available and for how

long
After 1399
To whom data/document is available
Author and colleagues
Under which criteria data/document could be used
For scientific reasons and By informing the author
From where data/document is obtainable
Responsible author
What processes are involved for a request to access data/document
Acceptance of Author and colleagues
Comments