

Clinical Trial Protocol

Iranian Registry of Clinical Trials

17 Sep 2026

A Comparative Study on the Effect of Handmade Del Nido Cardioplegia Solution with Handmade St. Thomas Cardioplegia Solution in terms of Quantitative Levels of Cardiac Troponin I and Phosphocreatine kinase MB in Ventricular Septal Defect Repair in Pediatric Cardiac Surgery.

Protocol summary

Study aim

A Comparative Study on the Effect of Handmade Del Nido Cardioplegia Solution with Handmade St. Thomas Cardioplegia Solution in terms of Quantitative Levels of Cardiac Troponin I and Phosphocreatine kinase MB in Ventricular Septal Defect Repair in Pediatric Cardiac Surgery.

Design

Randomized, parallel, and blind clinical trials.

Settings and conduct

Sixty patients under the age of 12 who were candidates for ventricular surgery in Chamran Hospital in Isfahan will be divided into two groups of 30 recipient recipients of St. Thomas and Del Nidou. A St. Thomas solution with a dose of 20 ml per kg and a temperature of 4 ° C and a Dilu Nido solution at a dose of 15 ml per kg and a ratio of four crystalloid units at 4 ° C and one unit of oxygenated oxygen in the patient is. Both solutions are surgically sterilized immediately before injection of cardioplegia solution and surgically injected through the syringe through a cardioplegia cannula inserted by the surgeon at the root of the aorta. Patients do not know their medication due to anesthesia during surgery.

Participants/Inclusion and exclusion criteria

Inclusion Criteria: Having less than 12 years of age
Obtaining informed consent written consent for all parents. Exclusion Criteria: Having a history of heart failure Having a history of myocardial infarction.

Intervention groups

Thirty patients with St. Thomas and 30 patients will also receive a perfusionist hand-made cardiopulmonary dendritic solution.

Main outcome variables

The low level of troponin I, the level of phospho creatine kinase.

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20171230038142N8**

Registration date: **2019-03-16, 1397/12/25**

Registration timing: **registered_while_recruiting**

Last update: **2019-03-16, 1397/12/25**

Update count: **0**

Registration date

2019-03-16, 1397/12/25

Registrant information

Name

Khosro Tavakol

Name of organization / entity

Country

Iran (Islamic Republic of)

Phone

+98 31 3792 9134

Email address

tavakol@nm.mui.ac.ir

Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2019-01-21, 1397/11/01

Expected recruitment end date

2019-05-20, 1398/02/30

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

A Comparative Study on the Effect of Handmade Del Nido Cardioplegia Solution with Handmade St. Thomas Cardioplegia Solution in terms of Quantitative Levels of Cardiac Troponin I and Phosphocreatine kinase MB in Ventricular Septal Defect Repair in Pediatric Cardiac Surgery.

Public title

The Effect of Handmade Del Nido Cardioplegia Solution with Handmade St. Thomas Cardioplegia Solution in terms of Quantitative Levels of Cardiac Troponin I and Phosphocreatine kinase MB.

Purpose

Treatment

Inclusion/Exclusion criteria

Inclusion criteria:

Having less than 12 years of age. Parental satisfaction from intervention.

Exclusion criteria:

Having a history of heart failure. Having a history of myocardial infarction.

Age

To 12 years old

Gender

Both

Phase

2-3

Groups that have been masked

- Participant

Sample size

Target sample size: 60

Randomization (investigator's opinion)

Randomized

Randomization description

Female or male patients undergoing surgical repair of large-inferior ventricular diaphragm were easily and conveniently distributed in Chamran Hospital in Isfahan. Then they are randomly assigned random allocation and random numbers in two groups of 30, which will be used in a group of St. Thomas's handmade solution and in another group of Del NIDO solution.

Blinding (investigator's opinion)

Single blinded

Blinding description

The samples are not aware of the therapeutic type and only the presenter is aware of the categorization of patients in each treatment group. Because these two solutions are injected during surgery, so patients are unaware of their drug type.

Placebo

Not used

Assignment

Parallel

Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee

Ethics Committee of Isfahan University of Medical Sciences

Street address

Isfahan University of Medical Sciences, Hezar Jarib Ave.

City

Isfahan

Province

Isfahan

Postal code

81746-73461

Approval date

2019-01-20, 1397/10/30

Ethics committee reference number

IR.MUI.MED.REC.1397.193

Health conditions studied

1

Description of health condition studied

Ventricular Septal Defect Repair

ICD-10 code

I23.2

ICD-10 code description

Ventricular septal defect as current complication following acute myocardial infarction

Primary outcomes

1

Description

Quantitative Levels of Cardiac Troponin I

Timepoint

Before surgery, six hours and 12 hours after surgery.

Method of measurement

Patient blood sample test

2

Description

Quantitative Levels of Phosphocreatine kinase MB

Timepoint

Before surgery, six hours and 12 hours after surgery.

Method of measurement

Patient blood sample test

Secondary outcomes

empty

Intervention groups

1

Description

Intervention group: Intervention group: 30 patients receiving St. Thomas cardiopulmonary by hand perfirngens with a dose of 20 ml per kg and at a temperature of 4 degrees Celsius. This solution is surgically dispensed immediately before injection of the cardioplegia solution sterilized. Then, through a cardioplegia cannula inserted by the surgeon at the root of the aorta, it is injected through the syringe. The injection rate of the cardiopulse solution is 30 to 40 mmHg and during 2 minutes and is controlled by pressure gauge in the injection route. This solution is injected into the patient in a single dose.

Category

Treatment - Surgery

2

Description

Intervention group: Intervention group: 30 patients with cardiogenic cardiopulmonary bypass grafting by perfusion. This solution is a dose of 15 ml per kilogram and a ratio of four crystalloid units at 4 ° C and one unit of complete oxygenated blood. Both solutions are surgically dispensed sterilized immediately after injection of the cardiopulmonary solution. A cardioplegia cannula inserted by the surgeon at the root of the aorta is injected through the syringe. The injection rate of the cardiopulse solution is 30 to 40 mmHg and in the It is in 2 minutes and is controlled by pressure gauge in the injection route. This solution is injected into the patient in a single dose.

Category

Treatment - Surgery

Recruitment centers

1

Recruitment center

Name of recruitment center

Shahid Chamran Hospital in Isfahan

Full name of responsible person

Hamid Bigdelian

Street address

Shahid Chamran Hospital, Salman Farsi Street.

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Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Esfahan University of Medical Sciences

Full name of responsible person

Ziba FarajZadegan

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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

Esfahan 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

Name of organization / entity

Esfahan University of Medical Sciences

Full name of responsible person

Hamid Bigdelian

Position

Associate Professor

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

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 data is unpublished after being unidentifiable and two years after the article is published.

When the data will become available and for how long

Two years after the publication and publication of the results.

To whom data/document is available

Assistants and Professors of the Department of Heart Surgery and Circulation Technology.

Under which criteria data/document could be used

To compare the effects of other handmade solutions on the low levels of troponin I and phospho creatine kinase MB with the present results.

From where data/document is obtainable

Accepting permission from the research vice president of Isfahan University of Medical Sciences.

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

Accepting permission from the research vice president of Isfahan University of Medical Sciences.

Comments