

Clinical Trial Protocol

Iranian Registry of Clinical Trials

27 Jul 2026

Inflammatory response and cardiac muscle damage markers in pediatric cardiac surgery: effect of two cardioplegia solutions “Del Nido” and “blood cardioplegia”

Protocol summary

Summary

(1) Objectives Assessment of the alterations in vital signs, blood biochemical parameters and inflammatory response in patients undergoing cardioplegia for cardiopulmonary bypass using Del Nido and modified saint Thomas solutions (2) Design Randomized and single-blinded (3) Setting and conduct Patients candidate for cardiopulmonary bypass surgery were randomly assigned in two groups. Their vital signs and demographic data will be recorded. After anesthesia induction and opening of the chest, cardioplegia will be performed using two different solutions, Del Nido and modified Saint Thomas. Plasma sampling will be performed in three different times, before incision, after declamping and 24 hours post-operation. ELISA method will be used for assaying IL-6, IL-8, IL-10, TNFa and cTnl markers. (4) Participants including major eligibility criteria Inclusion criteria: informed consent of guardians; weight below or equal to 15 kg; candidate for cardiopulmonary bypass surgery; Congenital tetralogy of Fallot; Pump time between 1 to 3 hours; operation time between 4 and 5 hours Exclusion criteria: patients' death; active infection; operation time more than 5 hours and pump time more than 3 hours (5) Intervention 1. Single-dose Del Nido cardioplegia solution 2. Multidose modified Saint Thomas cardioplegia solution (6) Main outcome measures (variables) Blood pressure, heart rate, respiratory rate, ICU stay, mechanical ventilation time, cytokines (IL-6, IL-8, IL-10 and TNFa), plasma level of cardiac marker cTnl and lactate

General information

Acronym

IRCT registration information

IRCT registration number: **IRCT2016042627617N1**
Registration date: **2016-06-12, 1395/03/23**

Registration timing: **registered_while_recruiting**

Last update:

Update count: **0**

Registration date

2016-06-12, 1395/03/23

Registrant information

Name

Hamidreza Pazoki-Toroudi

Name of organization / entity

Iran University of Medical Sciences

Country

Iran (Islamic Republic of)

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Email address

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Recruitment status

Recruitment complete

Funding source

Rajaei Cardiovascular and Medical Center, Iran University of Medical Sciences

Expected recruitment start date

2016-02-20, 1394/12/01

Expected recruitment end date

2016-07-08, 1395/04/18

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Inflammatory response and cardiac muscle damage markers in pediatric cardiac surgery: effect of two

cardioplegia solutions “Del Nido” and “blood cardioplegia”

Public title

Inflammatory response and cardiac muscle damage markers in pediatric cardiac surgery: effect of two cardioplegia solutions “Del Nido” and “blood cardioplegia”

Purpose

Treatment

Inclusion/Exclusion criteria

informed consent of guardians; weight below or equal to 15 kg; candidate for cardiopulmonary bypass surgery; Congenital tetralogy of Fallot; Pump time between 1 to 3 hours; operation time between 4 and 5 hours

Age

From **4 months** old to **5 years** old

Gender

Both

Phase

2-3

Groups that have been masked

No information

Sample size

Target sample size: **30**

Randomization (investigator's opinion)

Randomized

Randomization description

Blinding (investigator's opinion)

Single blinded

Blinding description

Placebo

Not used

Assignment

Parallel

Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee

Rajaei cardiovascular and medical center ethics committee

Street address

Niyayesh cross, Valiasr St., Tehran, Iran

City

Tehran

Postal code

1996911151

Approval date

2015-02-20, 1393/12/01

Ethics committee reference number

RHC.AC.IR.REC.1393.12

Health conditions studied

1

Description of health condition studied

Tetralogy of Fallot, Congenital Heart Diseases

ICD-10 code

Q21.3

ICD-10 code description

Ventricular septal defect with pulmonary stenosis or atresia, dextroposition of aorta and hypertrophy of right ventricle.

Primary outcomes

1

Description

cardiac troponin I (cTnI)

Timepoint

before operation, after declamp and 24 hours post-operation

Method of measurement

ELISA method

2

Description

il-6

Timepoint

Before surgery, after declamp and 24 hours post ICU entrance

Method of measurement

ELISA method on plasma

3

Description

IL-8

Timepoint

Before surgery, after declamp and 24 hours post ICU entrance

Method of measurement

ELISA method on plasma

4

Description

IL-10

Timepoint

before operation, after declamp and 24 hours post-operation

Method of measurement

ELISA method on plasma

5

Description

TNFa

Timepoint

before operation, after declamp and 24 hours post-operation

Method of measurement

6

Description

Heart rate

Timepoint

every 3 hours from operation start until 24 hours post-operation

Method of measurement

Vital sign monitoring system

7

Description

blood pressure

Timepoint

every 3 hours from operation start until 24 hours post-operation

Method of measurement

Vital sign monitoring system

Secondary outcomes

empty

Intervention groups

1

Description

Del Nido cardioplegia: a cardioplegia solution containing 1:4 ratio of patients oxygenated blood to crystalloid part which is administered in single dose and antegrade manner.

Category

Treatment - Drugs

2

Description

modified St. Thomas' solution which consist of a 4 parts of patients oxygenated blood and one part of crystalloid solution administered every 20 minutes in anegrade manner.

Category

Treatment - Drugs

Recruitment centers

1

Recruitment center

Name of recruitment center

Rajaei cardiovascular and medical center

Full name of responsible person

Farhad Gorjipour

Street address

Niayesh cross, Valiasr St.

City

Tehran

Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Vice chancellor for research, Administrative building, Rajaei cardiovascular and medical center

Full name of responsible person

Dr Gholampourdehaki

Street address

Niayesh crossroad, Valiasr st.

City

Tehran

Grant name

Grant code / Reference number

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

Yes

Title of funding source

Vice chancellor for research, Administrative building, Rajaei cardiovascular and medical center

Proportion provided by this source

100

Public or private sector

empty

Domestic or foreign origin

empty

Category of foreign source of funding

empty

Country of origin

Type of organization providing the funding

empty

Person responsible for general inquiries

Contact

Name of organization / entity

Rajaei Cardiovascular and Medical Center

Full name of responsible person

Dr Maziar Gholampour Dehaki

Position

Pediatric cardiovascular surgeon

Other areas of specialty/work

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Person responsible for scientific inquiries

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Name of organization / entity

Rajaei Cardiovascular and Medical Center

Full name of responsible person

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Position

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Web page address**Sharing plan****Deidentified Individual Participant Data Set (IPD)**

empty

Study Protocol

empty

Statistical Analysis Plan

empty

Informed Consent Form

empty

Clinical Study Report

empty

Analytic Code

empty

Data Dictionary

empty