Clinical Trial Protocol
Iranian Registry of Clinical Trials

18 Sep 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 cTnI 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 cTnI 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)

Phone

+98 21 8670 2708

Email address

pazoki49@gmail.com

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-operarion
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-operarion
Method of measurement
ELISA method on plasma

5

Description
TNFa
Timepoint
before operation, after declamp and 24 hours post-operarion
Method of measurement

ELISA method on plasma

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 crystaloid 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
Street address
Niyayesh Crossroad, Valiasr St
City
Tehran
Postal code
Phone
+98 21 2392 2169
Fax
Email
drgholampour@yahoo.com
Web page address

Person responsible for scientific 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
Street address
Niyayesh crossroad, Valiasr St.
City
Tehran
Postal code
Phone
+98 21 2392 2169
Fax
Email
drgholampour@yahoo.com
Web page address

Person responsible for updating data

Contact
Name of organization / entity
Iran University of Medical Sciences
Full name of responsible person
Fazel Gorjipour
Position
Other areas of specialty/work
Street address
Next to Milad Tower, Hemmat Highway
City
Tehran
Postal code
Phone
+98 21 8670 2708
Fax
Email
fgorjipour@gmail.com
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