

Clinical Trial Protocol

Iranian Registry of Clinical Trials

19 Sep 2026

Effect of Reducing the Intervals Between Two Injections of Del Nido Cardioplegia on Clinical Outcomes of Pediatrics with Tetralogy of Fallot Who Undergoing Cardiopulmonary Bypass

Protocol summary

Study aim

Determining the effect of reducing the time interval between two injections of Del Nido cardioplegia on the clinical outcomes of children undergoing complete tetralogy of Fallot repair surgery

Design

A clinical trial with a control group, with parallel groups, single-blind, randomized, phase 3 on 44 patients. Create a Randomization list software is used for randomization.

Settings and conduct

This study will be performed in Shahid Rajaei Cardiovascular Educational, Research and Treatment Center in 1401 in children. The study population will include all patients with congenital tetralogy disorder of Fallot and undergo open heart surgery with cardiopulmonary bypass and weigh less than 10 kg.

Participants/Inclusion and exclusion criteria

- 1) Parents' consent to participate in the research project
- 2) Sick infants up to 10 kg candidate for open-heart surgery
- 3) Aortic clamp duration between 60 to 180 minutes
- 4) Sternotomy
- 5) No intubation before surgery
- 6) Elective surgery

Intervention groups

In the intervention group, the interval between two doses of Del Nido cardioplegia will be reduced to 40 minutes. Patients in the control group will receive Del Nido cardioplegia every 60 minutes.

Main outcome variables

Evaluation of coronary sinus lactate, troponin, creatine phosphokinase

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20220424054638N1**

Registration date: **2022-06-22, 1401/04/01**

Registration timing: **registered_while_recruiting**

Last update: **2022-06-22, 1401/04/01**

Update count: **0**

Registration date

2022-06-22, 1401/04/01

Registrant information

Name

Yalda Asheghi

Name of organization / entity

Rajayi cardiovascular center

Country

Iran (Islamic Republic of)

Phone

+98 41 3383 9021

Email address

yaldaasheghi@rhc.ac.ir

Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2022-06-22, 1401/04/01

Expected recruitment end date

2022-07-23, 1401/05/01

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Effect of Reducing the Intervals Between Two Injections of Del Nido Cardioplegia on Clinical Outcomes of Pediatrics with Tetralogy of Fallot Who Undergoing

Public title

The effect of reducing the time interval between two injections of Del Nido cardioplegia on clinical outcomes

Purpose

Treatment

Inclusion/Exclusion criteria

Inclusion criteria:

Cardiac Surgery in Children with Tetralogy of Fallot
Undergoing Cardiopulmonary bypass Weighing Less than 10 kg
The Time of Cross-clamping Between 60-180 Minute
Obtain Informed Consent from Parents
Sternotomy Lack of Intubation before Surgery
Elective Surgery

Exclusion criteria:

Severe Hypothermia below 25 ° C

Age

No age limit

Gender

Both

Phase

3

Groups that have been masked

- Participant

Sample size

Target sample size: **44**

Randomization (investigator's opinion)

Randomized

Randomization description

Patients will be randomly divided into 4 permutation blocks using size 4 randomized alternation list intervention (control including 11 blocks of 4, with 4, 3, 2, 1 = Sequence within blocks). For example, the first 4 blocks are A-B-B-B. This means that the first patient was selected according to the randomization of the program (A) and the intervention will be performed on this patient. The second patient (B) was selected, as a control group member and so on.

Blinding (investigator's opinion)

Single blinded

Blinding description

This study is a randomized controlled clinical trial with a single blind (patient not knowing about the intervention) and after obtaining the informed consent of the patient's parents and observing the admission cases, the patient is anesthetized due to surgery and intervention.

Placebo

Not used

Assignment

Parallel

Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee

Ethics Committee of Shahid Rajaei Cardiovascular University

Street address

Shaheed Rajaie Cardiovascular Medical and Research Center Valiasr Ave Niayesh Intersection Tehran Iran

City

Tehran

Province

Tehran

Postal code

1995614331

Approval date

2021-12-04, 1400/09/13

Ethics committee reference number

IR.RHC.REC.1400.080

Health conditions studied

1

Description of health condition studied

Patients with congenital tetralogy of Fallot

ICD-10 code

Q21.3

ICD-10 code description

Tetralogy of Fallot

Primary outcomes

1

Description

Troponin

Timepoint

Before the intervention, enter the intensive care unit and 24 hours later

Method of measurement

Laboratory kits

Secondary outcomes

empty

Intervention groups

1

Description

"Intervention group:" In the intervention group, the interval between two doses of Del Nido cardioplegia will be reduced to 40 minutes. The first dose of cardioplegia in all patients will be 20 ml / kg and the second dose will be half of the first dose. The temperature of cardioplegia will be between 8-12 degrees Celsius and will be injected antegradically after aortic clamping in the aortic root.

Category

Other

2

Description

"Control group:" In the control group, del Nido cardioplegia will be injected as usual ,every 60 minutes. The first dose of cardioplegia in all patients will be 20 ml / kg and the second dose will be half of the first dose. The temperature of cardioplegia will be between 8-12 degrees Celsius and will be injected antegradically after aortic clamping in the aortic root.

Category

N/A

Recruitment centers

1

Recruitment center

Name of recruitment center

Shahid Rajaei Cardiovascular Hospital

Full name of responsible person

Yalda Asheghi

Street address

Shahid Rajaei Cardiovascular Training, Research and Treatment Center, Vali Asr St. Tehran

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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

Private

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

Shahid Rajayi cardiovascular center

Full name of responsible person

Yalda Asheghi

Position

Master Student

Latest degree

Bachelor

Other areas of specialty/work

Anesthesia

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Person responsible for scientific inquiries

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Person responsible for updating data

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Sharing plan

Deidentified Individual Participant Data Set (IPD)

No - There is not a plan to make this available

Justification/reason for indecision/not sharing IPD

There is no more information

Study Protocol

Undecided - It is not yet known if there will be a plan to
make this available

Statistical Analysis Plan

Undecided - It is not yet known if there will be a plan to
make this available

Informed Consent Form

No - There is not a plan to make this available

Clinical Study Report

Undecided - It is not yet known if there will be a plan to
make this available

Analytic Code

Undecided - It is not yet known if there will be a plan to
make this available

Data Dictionary

Undecided - It is not yet known if there will be a plan to
make this available