

Clinical Trial Protocol

Iranian Registry of Clinical Trials

18 Sep 2026

Assessing The Effects Of Mild And Moderate Hypothermia On The Cerebral Oxymetry In Acyanotic Congenital Heart Disease Under The Cardiopulmonary Bypass

Protocol summary

Study aim

The effect of mild to moderate hypothermia on changes in cerebral oxygenation in children undergoing surgery for Acyanotic congenital heart disease

Design

Random; a blind; Quadruple blocks; 64 patients

Settings and conduct

The nasopharyngeal temperature will be maintained above 35 degrees for the time before the onset of cardiopulmonary bypass. For each child, 5 measurements are performed at different intervals: 1- at the time after induction of anesthesia (baseline value), 2- at the time of cooling up to 34 degrees Celsius, 3- at the time of the lowest level of cooling (first group 32 Degrees Celsius), (the second group 28 degrees Celsius), 4-during reheating (above 34 degrees Celsius), 5-after CPB completion.

Participants/Inclusion and exclusion criteria

Inclusion criteria:: children who are candidates for non-cyanotic congenital heart disease surgery; children aged 1 day to 14 years; candidates for open heart surgery under the cardiopulmonary system (CPB); weight range between 5 and 20 kg. Exclusion criteria: history of neurological diseases, liver or kidney failure (creatinine above 2 mg / dL), preoperative anemia; history of cardiopulmonary resuscitation; emergency cardiac surgery, instability of hemodynamic status during the operation and decrease in temperature in the operation below the desired temperature.

Intervention groups

Mild hypothermia (32° C) group; moderate hypothermia (28° C) group.

Main outcome variables

Evaluation of rso2 changes; Evaluation of lactate changes; Percentage of frequency of neurological complications; Evaluation of postoperative intubation duration

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20201217049741N1**

Registration date: **2021-01-10, 1399/10/21**

Registration timing: **registered_while_recruiting**

Last update: **2021-01-10, 1399/10/21**

Update count: **0**

Registration date

2021-01-10, 1399/10/21

Registrant information

Name

Mehran Jafarian

Name of organization / entity

Shaheed Rajaie Heart Center

Country

Iran (Islamic Republic of)

Phone

+98 21 3384 9956

Email address

mehran-jafarian@rhc.ac.ir

Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2021-01-09, 1399/10/20

Expected recruitment end date

2021-02-08, 1399/11/20

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title
Assessing The Effects Of Mild And Moderate Hypothermia On The Cerebral Oxymetry In Acyanotic Congenital Heart Disease Under The Cardiopulmonary Bypass

Public title
Assessing The Effects Of Mild And Moderate Hypothermia On The Cerebral Oxymetry In Acyanotic Congenital Heart Disease Under The Cardiopulmonary Bypass

Purpose
Supportive

Inclusion/Exclusion criteria
Inclusion criteria:
 Children 1 day to 14 years old undergoing surgery for Acyanotic congenital heart disease with pulmonary heart bypass Children weighing 5 to 20 kg No history of neurological diseases No hepatic or renal insufficiency (creatinine above 2 mg / dL) No preoperative anemia No history of preoperative cardiopulmonary resuscitation Parents' consent to participate in the research project
Exclusion criteria:
 Hemodynamic instability Emergency heart surgery Lower the temperature during operation to below the desired temperature

Age
From **1 day** old to **14 years** old

Gender
Both

Phase
N/A

Groups that have been masked

- Participant

Sample size
Target sample size: **64**

Randomization (investigator's opinion)
Randomized

Randomization description
Assignment of individuals to study groups was done in a randomized block method using 4 blocks. This work was done with the relevant software by the professor of statistics. In each block, there were 2 people belonging to group A and two people belonging to group B, whose order was random and the blocks were selected using a table of random numbers.

Blinding (investigator's opinion)
Single blinded

Blinding description
Patients' parents are given explanations about the study and the two groups to be studied, and then they are given consent to enter the study, but they are not told which group they are in.

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 Heart Hospital, Tehran

Street address

Valiasr St., the intersection of Niayesh Shahid Rajaei Heart Hospital

City

Tehran

Province

Tehran

Postal code

1995614331

Approval date

2020-01-25, 1398/11/05

Ethics committee reference number

IR.RHC.REC.1398.082

Health conditions studied

1

Description of health condition studied

Congenital Acyanotic heart disease

ICD-10 code

ICD-10 code description

Primary outcomes

1

Description

Cerebral oxygenation

Timepoint

1- At the time after induction of anesthesia (baseline value), 2- At the time of cooling up to 34 degrees Celsius, 3- At the lowest level of cooling (first group 32 degrees Celsius), (second group 28 degrees Celsius), 4 - At the time of reheating (above 34 degrees Celsius), 5-after CPB.

Method of measurement

Based on the amount of INVOS

2

Description

Blood lactate

Timepoint

1- At the time after induction of anesthesia (baseline value), 2- At the time of cooling up to 34 degrees Celsius, 3- At the lowest level of cooling (first group 32 degrees Celsius), (second group 28 degrees Celsius), 4 - At the time of reheating (above 34 degrees Celsius), 5-after CPB.

Method of measurement

Laboratory kits

3**Description**

Incidence of neurological complications

Timepoint

From postoperative time to discharge

Method of measurement

Based on patient records

4**Description**

Average intubation time

Timepoint

From the time of surgery to Extubation

Method of measurement

Based on patient records

Secondary outcomes

empty

Intervention groups**1****Description**

Intervention group: Patients in the mild hypothermia group (32 ° C) are treated as follows. The nasopharyngeal temperature will be maintained above 35 degrees for the time before the onset of cardiopulmonary bypass. For each child, 5 measurements are performed at different intervals: 1- at the time after induction of anesthesia (baseline value), 2- at the time of cooling up to 34 degrees Celsius, 3- at the time of the lowest level of cooling (first group 32 Degrees Celsius), 4- at reheating time (above 34 degrees Celsius), 5- after CPB completion.

Category

Other

2**Description**

Intervention group: Patients in moderate hypothermia (28 ° C) are treated as follows. The nasopharyngeal temperature will be maintained above 35 degrees for the time before the onset of cardiopulmonary bypass. For each child, 5 measurements are performed at different intervals: 1- at the time after induction of anesthesia (baseline value), 2- at the time of cooling up to 34 degrees Celsius, 3- at the time of the lowest level of cooling (28 degrees Celsius), 4- at reheating time (above 34 degrees Celsius), 5- after CPB completion.

Category

Other

Recruitment centers**1****Recruitment center****Name of recruitment center**

Shahid Rajaei Heart Hospital, Tehran

Full name of responsible person

Mehran Jafarian

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Valiasr St., Niayesh Intersection, Shahid Rajaei Heart Hospital

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Sponsors / Funding sources**1****Sponsor****Name of organization / entity**

Shahid Rajaei Heart Hospital, Tehran

Full name of responsible person

Dr. Majid Maleki

Street address

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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

Shahid Rajaei Heart Hospital, Tehran

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**

Shahid Rajaei Cardiovascular Hospital, Tehran

Full name of responsible person

Mehran Jafarian

Position

Master student of perfusion

Latest degree

Bachelor

Other areas of specialty/work

Nursery

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Person responsible for scientific inquiries**Contact****Name of organization / entity**

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Full name of responsible person

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Position

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Latest degree

Bachelor

Other areas of specialty/work

Nursery

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Person responsible for updating data**Contact****Name of organization / entity**

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Full name of responsible person

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Position

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Sharing plan**Deidentified Individual Participant Data Set (IPD)**

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

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

Undecided - It is not yet known if there will be 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