Clinical Trial Protocol
Iranian Registry of Clinical Trials

30 Jun 2026

The effect of subzero balanced –modified ultrafiltration technique on chemical and clinical outcomes in cardiopulmonary bypass of pediatrics undergoing cardiac surgery

Protocol summary

Study aim

By using this technique, we try to increase the patient's hematocrit to at least 33% at the end of surgery so that coagulation factors and platelets are also concentrated while eliminating the need for blood transfusion. By performing both intermittent and continuous methods, more inflammatory mediators are eliminated. it's a step towards introducing an optimal technique in pediatric hemofiltration, which is practical and important for the perfusion community.

Design

The clinical trial had a control group, with parallel groups, two-way blind, without random phase. Over 80 patients. Randomized according to permutation block table.

Settings and conduct

In the heart surgery ward of Shahid Faghihi Hospital in Shiraz. Blinding of ICU nurses and patients with their unawareness of the processes.

Participants/Inclusion and exclusion criteria

Children who weigh at least 3 kg at birth and weigh a maximum of 30 kg. have no kidney abnormalities and are not born prematurely. Have normal blood potassium and preferably no more than 50% hematocrit before surgery, although high hematocrit must be reduced to about 25% during heart surgery.

Intervention groups

In the intervention group, patients receive isotonic fluid continuously during surgery and a little more than the volume of injected fluid is expelled from their blood by a concentrator that has its own unique circuitry. At the end of the surgery, for about 10 minutes, the blood is also filtrated. In the control group, the excess fluid is still excreted by the concentrator, but with a simpler circuit and intermittent times and with perfusionist discretion. Also, the final concentration is not done at the end of the operation.

Main outcome variables

Increased excretion of inflammatory mediators: Increased hematocrit after bypass: Blood bank saving: Introduction of a new and practical circuit for pediatric heart surgery bypass

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20211219053454N1**
Registration date: **2022-01-04, 1400/10/14**
Registration timing: **prospective**

Last update: **2022-01-04, 1400/10/14**
Update count: **0**

Registration date

2022-01-04, 1400/10/14

Registrant information

Name

mehrtash shadmehr

Name of organization / entity

Country

Iran (Islamic Republic of)

Phone

+98 21 4482 5838

Email address

mehrtash.shad@yahoo.com

Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2022-02-20, 1400/12/01

Expected recruitment end date

2022-06-22, 1401/04/01

Actual recruitment start date
empty
Actual recruitment end date
empty
Trial completion date
empty

Scientific title
The effect of subzero balanced –modified ultrafiltration technique on chemical and clinical outcomes in cardiopulmonary bypass of pediatrics undergoing cardiac surgery

Public title
The effect of subzero balanced –modified ultrafiltration technique on chemical and clinical outcomes in cardiopulmonary bypass of pediatrics undergoing cardiac surgery
Purpose
Prevention
Inclusion/Exclusion criteria
Inclusion criteria:
weight between 3 to 30 Kg No renal dysfanction being born term normal blood potassium No transfusions of blood and its products prior to operation age between 0 to 18
Exclusion criteria:
weight under 3 and above 3 kg renal dysfunction being born preterm abnormal potassium transfusion of blood and its products age above 18 administered diuretic prior to operation
Age
From **1 month** old to **18 years** old
Gender
Both

Phase
N/A
Groups that have been masked

- Participant
- Care provider
- Outcome assessor

Sample size
Target sample size: **80**
Randomization (investigator's opinion)
Randomized
Randomization description
To randomly assign samples to each group, a random list obtained from a random number table by permutation block method is used. After receiving the patient in the operating room, his / her characteristics and tests are checked. If he / she meets the conditions for admission to the study, he / she will be assigned to one of the intervention or control groups according to the table of random numbers received from randomization.com.
Blinding (investigator's opinion)
Double blinded
Blinding description
Due to the nature of the study, children undergo surgery are not and will not be aware of the techniques performed during operation. Also, ICU nurses who record most of the information assessed after surgery are not aware of the process and techniques performed in the operating room.
Placebo
Not used
Assignment
Parallel
Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee
Name of ethics committee
Ethics committee of Shiraz University of Medical Sciences
Street address
Zand st. Namazi sq. Shiraz
City
Shiraz
Province
Fars
Postal code
7134814336
Approval date
2021-11-16, 1400/08/25
Ethics committee reference number
IR.SUMS.MED.REC.1400.357

Health conditions studied

1

Description of health condition studied
Ventricular septal defect
ICD-10 code
Q21.0
ICD-10 code description
Ventricular septal defect

2

Description of health condition studied
Congenital heart disease
ICD-10 code
Q24.9
ICD-10 code description
Congenital malformation of heart, unspecified

3

Description of health condition studied
Tetralogy of Fallot
ICD-10 code
Q21.3
ICD-10 code description
Tetralogy of Fallot

Primary outcomes

1

Description
Changes in blood potassium during bypass.
Timepoint
Measuring the amount of potassium before the bypass and at half-hour intervals during bypass until its end.
Method of measurement
Potassium testing is performed with an ABG measuring device in the cardiac operating room.

2

Description
Measuring the amount of blood / products after operation
Timepoint
Daily
Method of measurement
Blood and products are in graduated bags that the amount injected is recorded by the ICU nurse

3

Description
Measurement of urinary output after surgery
Timepoint
Daily
Method of measurement
Urine is emptied into graduated containers, which are recorded by the ICU nurse on an hourly basis. We calculate the average daily urine output per person.

4

Description
Evaluation the incidence of cardiac dysrhythmia
Timepoint
Constantly
Method of measurement
By ECG monitoring. In case of occurrence, it will be recorded.

Secondary outcomes

1

Description
ICU length of stay
Timepoint
Daily
Method of measurement
The patient entering and leaving the ICU is recorded.

2

Description
Evaluating the GFR during ICU stay
Timepoint
Daily
Method of measurement
GFR determination is calculated by the formula (Schwartz) which has a specific coefficient according to age, height, sex and creatinine.

3

Description
Measurement of blood transfusion during surgery
Timepoint
Hourly during surgery
Method of measurement
The blood is in graduated bags where the amount transfused is recorded.

Intervention groups

1

Description
Intervention group: Children undergoing heart surgery who receive a sub-zero ultrafiltration technique continuously during the bypass, and after the cardiac bypass is completed, the modified ultrafiltration technique will be performed on them for about 10 minutes.
Category
Prevention

2

Description
Control group: Children undergoing heart surgery who undergo the conventional ultrafiltration technique when needed and at the discretion of the perfusionist
Category
Prevention

Recruitment centers

1

Recruitment center
Name of recruitment center
Shahid Faghihi hospital
Full name of responsible person
Khalil Zarrabi
Street address
Zand st
City
Shiraz
Province
Fars
Postal code
7134846114
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+98 71 3235 1087
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Email
Faghihihsp@sums.ac.ir
Web page address
https://faghihi.sums.ac.ir

Sponsors / Funding sources

1

Sponsor
Name of organization / entity
Shiraz University of Medical Sciences
Full name of responsible person
Mahtab Memarpoor
Street address
Zand st
City
Shiraz
Province
Fars
Postal code
7134845794
Phone
+98 71 3230 5887
Email
vcrdep@sums.ac.ir
Web page address
http://www.reaserch.sums.ac.ir
Grant name
Grant code / Reference number
Is the source of funding the same sponsor organization/entity?
Yes
Title of funding source
Shiraz 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
Shiraz University of Medical Sciences
Full name of responsible person
Khalil Zarrabi
Position
Associate professor of cardiovascular surgery
Latest degree
Subspecialist
Other areas of specialty/work
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Person responsible for scientific inquiries

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Person responsible for updating data

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Latest degree
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Zarrabisx@gmail.com

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

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

Data Dictionary

Not applicable

Title and more details about the data/document

Demographic informations

When the data will become available and for how long

Start of access period from 1402

To whom data/document is available

People working and researching in the field of cardiovascular surgery

Under which criteria data/document could be used

All analyzes are allowed

From where data/document is obtainable

Mr. Mehrtash Shadmehr +989366875622
Mehrtash.shad@yahoo.com

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

Send email and coordinate

Comments