

# 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 dysfunction 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

##### Phone

+98 71 3235 1087

##### Fax

+98 71 3233 1634

##### 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 Memarpour

**Street address**

Zand st

**City**

Shiraz

**Province**

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**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**

Cardiology

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## Person responsible for scientific inquiries

### Contact

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**Latest degree**

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## Person responsible for updating data

### Contact

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**Position**

Associate professor

**Latest degree**

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**Other areas of specialty/work**

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## 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**