Clinical Trial Protocol
Iranian Registry of Clinical Trials

16 Sep 2026

Effect of zero-balanced ultrafiltration of priming blood on pro-calcitonin and respiratory function in the infants undergoing cardiopulmonary bypass

Protocol summary

Study aim
Comparing the mean arterial blood parameters, pro-calcitonin, mechanical ventilation, pulmonary compliance and respiratory index in patients with zero-balanced ultrafiltration (Z_BUF) prime compared to control group.

Design
This is a randomized controlled clinical trial with parallel design. We apply balanced block randomization method (block of four) for randomization. Randomization sequence will be give to a person out of the research team in order to perform concealment.

Settings and conduct
This is a single center open-labeled study. The study conducted in cardiac surgery operation rooms and post-op ICUs in Rajaie Heart Center, Tehran, Iran.

Participants/Inclusion and exclusion criteria
Inclusion Criteria: pregnancy duration equal or more than 37 weeks Parental consent weight under 10 kg open heart surgery no other major congenital anomaly affected post-op recovery No previous sternotomy Exclusion criteria: cardiac arrest during the operation using defibrillator during the operation aortic clamp time less than 30 minutes

Intervention groups
Intervention group: standard ultrafiltration AND zero-balanced ultrafiltration on the prime solution during cardiopulmonary bypass pump (CPB) Control group: standard ultrafiltration on the prime solution during cardiopulmonary bypass pump (CPB)

Main outcome variables
mean level of serum procalcitonin; Respiratory Index; pulmonary compliance

General information

Reason for update

Acronym

IRCT registration information
IRCT registration number: **IRCT20180110038301N1**
Registration date: **2018-05-21, 1397/02/31**
Registration timing: **retrospective**

Last update: **2018-05-21, 1397/02/31**
Update count: **0**

Registration date
2018-05-21, 1397/02/31

Registrant information

Name
sana niknam

Name of organization / entity
Shahid rajaie cardiovaschular medical & researchcenter

Country
Iran (Islamic Republic of)

Phone
+98 21 2392 2424

Email address
sananiknam@rhc.ac.ir

Recruitment status
Recruitment complete

Funding source

Expected recruitment start date
2017-09-06, 1396/06/15

Expected recruitment end date
2018-02-19, 1396/11/30

Actual recruitment start date
2017-09-06, 1396/06/15

Actual recruitment end date
2018-02-19, 1396/11/30

Trial completion date
empty

Scientific title

Effect of zero-balanced ultrafiltration of priming blood on pro-calcitonin and respiratory function in the infants undergoing cardiopulmonary bypass

Public title
Effect of prime ultrafiltration on pro-calcitonin and respiratory function in the infants undergoing cardiopulmonary bypass
Purpose
Treatment
Inclusion/Exclusion criteria
Inclusion criteria:
pregnancy duration equal or more than 37 weeks
Parental consent weight under 10 kg open heart surgery
no other major congenital anomaly affected post-op recovery No previous sternotomy
Exclusion criteria:
cardiac arrest during the operation using defibrillator during the operation aortic clamp time less than 30 minutes
Age
To **18 months** old
Gender
Both

Phase
2
Groups that have been masked
No information
Sample size
Target sample size: **60**
More than 1 sample in each individual
Number of samples in each individual: **4**
blood biochemistry and procalcitonin,respiratory function
Actual sample size reached: **60**
More than 1 sample in each individual
Actual sample size in each individual: **4**
blood biochemistry and procalcitonin,respiratory function
Randomization (investigator's opinion)
Randomized
Randomization description
We apply balanced block randomization method (block of four) for randomization. Randomization sequence will be give to a person out of the research team in order to perform concealment.
Blinding (investigator's opinion)
Not blinded
Blinding description
Placebo
Not used
Assignment
Parallel
Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee
Name of ethics committee
Ethics committee of Rajaie cardiovascular medical and research center
Street address
Valiasr Ave Niayesh Intersection
City
Tehran
Province
Tehran
Postal code
1995614331
Approval date
2017-10-14, 1396/07/22
Ethics committee reference number
RHC.AC.IR.REC.1396.45

Health conditions studied

1

Description of health condition studied
infants required cardiac surgery with cardiopulmonary bypass pump (due to congenital anomalies)
ICD-10 code
Q24
ICD-10 code description
Other congenital malformations of heart

Primary outcomes

1

Description
mean level of serum procalcitonin
Timepoint
first and 24 hour after admission to ICU
Method of measurement
Electro-chemiluminescence immunoassay (ECLIA) method via cobas, Roshe

2

Description
Respiratory Index
Timepoint
pre-operative after induction of anesthesia, at the end of operation and 2 hours after ICU admission
Method of measurement
Ventilator output

3

Description
pulmonary compliance
Timepoint
pre-operative after induction of anesthesia, at the end of operation and 2 hours after ICU admission
Method of measurement
Ventilator output

Secondary outcomes

empty

Intervention groups

1

Description
Intervention group: standard ultrafiltration AND zero-balanced ultrafiltration on the prime solution during cardiopulmonary bypass pump (CPB)
Category
Treatment - Other

2

Description
Control group: standard ultrafiltration on the prime solution during cardiopulmonary bypass pump (CPB)
Category
Treatment - Other

Recruitment centers

1

Recruitment center
Name of recruitment center
Rajaie Cardiovascular Medical and Research Center
Full name of responsible person
Maziar Gholampour
Street address
Valiasr Ave Niayesh Intersection
City
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1995614331
Phone
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Email
sananiknam@rhc.ac.ir

Sponsors / Funding sources

1

Sponsor
Name of organization / entity
Rajaie Cardiovascular Medical and Research Center
Full name of responsible person
Maziar Gholampour
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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
Rajaie Cardiovascular Medical and Research Center
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
Rajaie Cardiovascular Medical and Research Center
Full name of responsible person
Sana Niknam
Position
Student
Latest degree
Master
Other areas of specialty/work
Nursery
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Person responsible for scientific inquiries

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Position
Professor
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Subspecialist
Other areas of specialty/work

cardiac surgery

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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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Latest degree

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Other areas of specialty/work

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sananiknam@rhc.ac.ir

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

No - There is not a plan to make this available

Analytic Code

No - There is not a plan to make this available

Data Dictionary

Yes - There is a plan to make this available

Title and more details about the data/document

Study protocol and De-identified Individual Participant Data Set (IPD) will be shared.

When the data will become available and for how long

Data will be available after publishing the relevant articles.

To whom data/document is available

All the researches in the biomedical field can propose their request about accessing data.

Under which criteria data/document could be used

For using the study data, it is necessary to make an agreement/collaboration contract between the applicants and primary investigator (PI).

From where data/document is obtainable

The applicants should proposed their request to the PI via the email.

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

Only the applications received via email will be considered and replied. For continuation , PI will contact the applicant's mobile.

Comments