

# Clinical Trial Protocol

## Iranian Registry of Clinical Trials

09 Jun 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

Tehran

##### Province

Tehran

##### Postal code

1995614331

##### Phone

+98 21 23921

##### 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

##### Street address

Valiasr Ave Niayesh Intersection

##### City

Tehran

##### Province

Tehran

##### Postal code

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#### Phone

+98 21 23921

#### Email

sananiknam@rhc.ac.ir

#### 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

##### Street address

Valiasr Ave Niayesh Intersection

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##### Province

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##### Postal code

1995614331

##### Phone

+98 21 23921

##### Email

sananiknam@rhc.ac.ir

## Person responsible for scientific inquiries

#### Contact

##### Name of organization / entity

Rajaie Cardiovascular Medical and Research Center

##### Full name of responsible person

Maziar Gholampour

##### Position

Professor

##### Latest degree

Subspecialist

##### Other areas of specialty/work

cardiac surgery

**Street address**

Valiasr Ave Niayesh Intersection

**City**

Tehran

**Province**

Tehran

**Postal code**

1995614331

**Phone**

+98 21 23921

**Email**

sananiknam@rhc.ac.ir

**Person responsible for updating data**

**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

**Street address**

Valiasr Ave Niayesh Intersection

**City**

Tehran

**Province**

Tehran

**Postal code**

1995614331

**Phone**

+98 21 23921

**Email**

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**