

Clinical Trial Protocol

Iranian Registry of Clinical Trials

26 Jul 2026

Compare the effects of 5% albumin dose versus 2% in prime solution on fluid balance in heart surgery on congenital heart disease in newborn and infant

Protocol summary

Study aim

Determine the relationship between 5% albumin dose and body fluid balance in newborn and infants

Design

Two arm parallel group randomised trial with blinded postoperative care and outcome assessment

Settings and conduct

The location of this research is in the operating room and pediatric cardiac care unit. In this study, pediatric cardiologist, cardiologist, perfusionist and nurses are blind to the study.

Participants/Inclusion and exclusion criteria

1. Parental consent to participate in the research project
2. The age of 5 day to 2year 3. Weight less than or equal to 10 kg 4. Patients candidated for open heart surgery 5. Congenital anomaly of the heart 6. Duration of pump for at least one hour and maximum three hours

Intervention groups

The intervention groups in this study are newborn and infants with congenital heart disease that are under the cardiovascular surgery Two groups in this study are a group of patients who use albumin 5% in prime solution. And the second group of patients who used albumin to 2% condiment in their prime solution

Main outcome variables

albumin

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20180522039787N1**

Registration date: **2018-08-27, 1397/06/05**

Registration timing: **retrospective**

Last update: **2018-08-27, 1397/06/05**

Update count: **0**

Registration date

2018-08-27, 1397/06/05

Registrant information

Name

Amirhosein Salehzade

Name of organization / entity

Rajaei Cardiovascular, Medical & Research Center

Country

Iran (Islamic Republic of)

Phone

+98 13 3554 5206

Email address

a.salehzade@rhc.ac.ir

Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2018-03-06, 1396/12/15

Expected recruitment end date

2018-06-20, 1397/03/30

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Compare the effects of 5% albumin dose versus 2% in prime solution on fluid balance in heart surgery on congenital heart disease in newborn and infant

Public title

effect of albumin in pediatric surgery

Purpose

Treatment

Inclusion/Exclusion criteria

Inclusion criteria:

Parental satisfaction regarding participation in research project
Age 5 days to 2 years
Weight less than or equal to 10 kg
Patients candidated for open heart surgery
Congenital anomaly of the heart
Duration of cardiopulmonary bypass[for at least one hour and maximum three hours

Exclusion criteria:

Deep hypothermia
low cardiac output
edema or ascites before surgery
Infection and inflammation known a week before surgery
emergency surgery
Not consenting parents to enter the trial

Age

From **5 days** old to **2 years** old

Gender

Both

Phase

3

Groups that have been masked

- Participant
- Care provider
- Outcome assessor
- Data analyser

Sample size

Target sample size: **60**

Randomization (investigator's opinion)

Randomized

Randomization description

In this study, a random block was used. Random units are individual. The randomization tool in this study is a random numbered table. The size of each block is 5.

Blinding (investigator's opinion)

Double blinded

Blinding description

In this study, after cardiac surgery, all specimens are under echocardiography to check for ascites and efusion, which the pediatric cardiologist, who is responsible for this task, is blind to the study. The respectable perfusionists and the relevant heart surgeon are also blind to the patients. Nurses also do not know how to share patients. But the main investigator who is responsible for recording data is not blind to the study. After determining the placement of the sample in the control group or the intervention, we prepare a sample of the primer solution. Regarding the used oxygenator, the serum level used for primers is different. For each 100 cc of serum, 5 g of albumin in the intervention group and 2 g in the control group are used to reach the desired crop. It should be noted that perfusionists who prepare prime solution for the patient are blind to the study.

Placebo

Not used

Assignment

Parallel

Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee

Ethics Committee at Shahid Rajaee Cardiology Hospital of Tehran

Street address

valiasr Ave. niayesh blvd. shahid rajae cardiovascular and research center

City

tehran

Province

Tehran

Postal code

6911151

Approval date

2018-02-17, 1396/11/28

Ethics committee reference number

RHC.AC.REC.1396.83

Health conditions studied

1

Description of health condition studied

congenital heart desease

ICD-10 code

Q25.0

ICD-10 code description

Patent ductus arteriosus

Primary outcomes

1

Description

albumin

Timepoint

At the beginning of the study (before the study started) -
Immediately in the intensive care unit - 24 hours later in the intensive care unit

Method of measurement

Albumin Measuring Laboratory Kit

2

Description

on fluid balance

Timepoint

At the beginning of the study (before the study started) -
Immediately in the intensive care unit - 24 hours later in the intensive care unit

Method of measurement

Laboratory kit measuring body electrolytes

Secondary outcomes

empty

Intervention groups

1

Description

The intervention group in this study is a patient with albumin concentration of 5% in prime solutions. First, the appropriate oxygenator is selected with the patient and is primed with a ringer serum. Corresponding to the amount of ringer serum used to reach 5% concentration of albumin in prime solution, 20% vial of albumin available in the hospital is used. The albumin has been used in 50cc vials at a concentration of 20% in the hospital. For example, if 200 cc of the ringer is used for the oxygenator prime, 10 g of albumin is added to the prime solution to achieve a 5% concentration of albumin in the patient's prime solution. Only in prime solution and once using albumin, then the process of preparing the patient and the equipment continues to proceed.

Category

Treatment - Devices

2

Description

Control group: The control group in this study is a patient with albumin concentration of 2% in prime solutions. First, the appropriate oxygenator is selected with the patient and is primed with a ringer serum. Corresponding to the amount of ringer serum used to reach 2% concentration of albumin in prime solution, 20% vial of albumin available in the hospital is used. The albumin has been used in 50cc vials at a concentration of 10% in the hospital. For example, if 200 cc of the ringer is used for the oxygenator prime, 4 g of albumin is added to the prime solution to achieve a 5% concentration of albumin in the patient's prime solution. Only in prime solution and once using albumin, then the process of preparing the patient and the equipment continues to proceed.

Category

Treatment - Devices

Recruitment centers

1

Recruitment center

Name of recruitment center

Shahid Rajae Cardiovascular and Research Center

Full name of responsible person

Amirhosein Salehzade

Street address

Shahid Rajae Heart Center.Valieasr Ave

City

Tehran

Province

Tehran

Postal code

1995614331

Phone

+98 21 23921

Fax

+98 21 2204 2026

Email

a.salehzade@rhc.ac.ir

Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Shahid Rajae Cardiovascular and Research Center

Full name of responsible person

Amirhosein Salehzade

Street address

Shahid Rajae Heart Center.Valieasr Ave

City

Tehran

Province

Tehran

Postal code

1995614331

Phone

+98 21 23921

Fax

+98 21 2204 2026

Email

a.salehzade@gmail.com

Grant name

Grant code / Reference number

Is the source of funding the same sponsor organization/entity?

Yes

Title of funding source

Shahid Rajae Cardiovascular 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

Shahid Rajae Cardiovascular and Research Center

Full name of responsible person

Amirhosein Salehzade

Position

Graduate Student of Perfusion

Latest degree

Bachelor

Other areas of specialty/work

Circulation Technology

Street address

Shahid Rajae Heart Center.Valieasr Ave

City
Tehran
Province
Tehran
Postal code
1995614331
Phone
+98 21 23921
Fax
+98 21 2204 2026
Email
a.salehzade@rhc.ac.ir

Person responsible for scientific inquiries

Contact

Name of organization / entity
Shahid Rajae Heart Center
Full name of responsible person
Amirhosein Salehzade
Position
Graduate Student of Perfusion
Latest degree
Bachelor
Other areas of specialty/work
Circulation Technology
Street address
Shahid Rajae Heart Center.Valieasr Ave
City
Tehran
Province
Tehran
Postal code
1995614331
Phone
+98 21 23921
Fax
+98 21 2204 2026
Email
a.salehzade@rhc.ac.ir

Person responsible for updating data

Contact

Name of organization / entity

Shahid Rajae Heart Center
Full name of responsible person
Amirhosein Salehzade
Position
Graduate Student of Perfusion
Latest degree
Bachelor
Other areas of specialty/work
Circulation Technology
Street address
Shahid Rajae Heart Center.Valieasr Ave
City
Tehran
Province
Tehran
Postal code
1995614331
Phone
+98 21 23921
Fax
+98 21 2204 2026
Email
a.salehzade@rhc.ac.ir
Web page address

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

Not applicable

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

No - There is not a plan to make this available

Data Dictionary

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