

Clinical Trial Protocol

Iranian Registry of Clinical Trials

30 Jul 2026

Comparison of the effect of receiving fresh blood or stored blood components on incidence of bleeding and hemodynamic changes in children with congenital heart diseases candidate for surgery

Protocol summary

Study aim

Comparison of the incidence of bleeding and hemodynamic changes after receiving fresh blood or stored blood components during cardiac surgery in children with congenital heart diseases

Design

This study is a non-randomized clinical trial without control group, with parallel groups. Children were divided in to two groups . The first group will receive fresh blood during operation and the second group will receive stored component during operation.

Settings and conduct

Children with congenital heart diseases who are candidate for cardiac surgery in Chamran hospital are divided in to two groups. Children will receive fresh blood or stored blood components during operation, . After operation volume of bleeding and hemodynamic variables are measured and compared between two groups.

Participants/Inclusion and exclusion criteria

Inclusion criteria:1)having acyanotic congenital heart disease, 2)candidate for cardiac surgery ,3)age between 1 month-5 years, 4)parent's willingness Exclusion criteria :1) sensitivity to Protamine

Intervention groups

The first intervention group: receiving fresh blood during operation The second intervention group: receiving stored components during operation

Main outcome variables

Bleeding, hemodynamic changes, prognosis

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20171104037209N2**

Registration date: **2018-03-12, 1396/12/21**

Registration timing: **prospective**

Last update: **2018-03-12, 1396/12/21**

Update count: **0**

Registration date

2018-03-12, 1396/12/21

Registrant information

Name

shima khamesipour

Name of organization / entity

Isfahan School of Medical Sciences

Country

Iran (Islamic Republic of)

Phone

+98 32403150

Email address

massoumigh@mui.ac.ir

Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2018-03-21, 1397/01/01

Expected recruitment end date

2019-03-21, 1398/01/01

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Comparison of the effect of receiving fresh blood or stored blood components on incidence of bleeding and hemodynamic changes in children with congenital heart

diseases candidate for surgery	
Public title	fresh blood and stored components in children cardiac surgery
Purpose	Treatment
Inclusion/Exclusion criteria	
Inclusion criteria:	Having age between 1 month- 5 years Having indication for cardiac surgery due to acyanotic congenial heart disease parent's willingness
Exclusion criteria:	Sensitivity to Protamine
Age	From 1 month old to 5 years old
Gender	Both
Phase	N/A
Groups that have been masked	No information
Sample size	Target sample size: 62
Randomization (investigator's opinion)	Not randomized
Randomization description	
Blinding (investigator's opinion)	Not blinded
Blinding description	
Placebo	Not used
Assignment	Parallel
Other design features	

Secondary Ids

empty

Ethics committees

<u>1</u>	
Ethics committee	
Name of ethics committee	Ethics committee of Isfahan University of Medical Sciene
Street address	Isfahan University of Medical Science, Hezar jarib street
City	Isfahan
Province	Isfahan
Postal code	8174673461
Approval date	2017-06-20, 1396/03/30
Ethics committee reference number	IR.MUI.REC.1396.3.974

Health conditions studied

<u>1</u>	
Description of health condition studied	Congenital Heart Disease
ICD-10 code	Q24.9
ICD-10 code description	Congenital malformation of heart, unspecified

Primary outcomes

<u>1</u>	
Description	Bleeding volume after operation
Timepoint	After operation in Intensive Care Unit
Method of measurement	Measuring drainage volume
<u>2</u>	
Description	Mean Arterial Pressure
Timepoint	After artery line insertion, during operation, in Intensive Care Unit
Method of measurement	Using blood pressure machine
<u>3</u>	
Description	Hemoglobin level
Timepoint	After artery line insertion, during operation, in Intensive Care Unit
Method of measurement	Spectrophotometer device

<u>4</u>	
Description	Hematocrit
Timepoint	After artery line insertion, during operation, in Intensive Care Unit
Method of measurement	Spectrophotometer device

Secondary outcomes

<u>1</u>	
Description	mortality
Timepoint	After operation
Method of measurement	observation

Intervention groups

1

Description

Intervention group: Receiving fresh blood during operation

Category

Treatment - Other

2

Description

Intervention group: Receiving stored components during operation

Category

Treatment - Other

Recruitment centers

1

Recruitment center

Name of recruitment center

Chamran hospital

Full name of responsible person

Gholamreza Massoumi

Street address

Chamran hospital, Moshtagh street

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Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Esfahan University of Medical Sciences

Full name of responsible person

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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

Esfahan 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

Esfahan University of Medical Sciences

Full name of responsible person

Athar Zandi

Position

resident

Latest degree

Medical doctor

Other areas of specialty/work

Anesthesiology

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