Clinical Trial Protocol
Iranian Registry of Clinical Trials

18 Sep 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

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Name of organization / entity
Isfahan School of Medical Sciences

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Iran (Islamic Republic of)

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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

1

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
Isfehan
Postal code
8174673461
Approval date
2017-06-20, 1396/03/30
Ethics committee reference number
IR.MUI.REC.1396.3.974

Health conditions studied

1

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

Primary outcomes

1

Description
Bleeding volume after operation
Timepoint
After operation in Intensive Care Unit
Method of measurement
Measuring drainage volume

2

Description
Mean Arterial Pressure
Timepoint
After artery line insertion, during operation, in Intensive Care Unit
Method of measurement
Using blood pressure machine

3

Description
Hemoglobin level
Timepoint
After artery line insertion, during operation, in Intensive Care Unit
Method of measurement
Spectrophotometer device

4

Description
Hematocrit
Timepoint
After artery line insertion, during operation, in Intensive Care Unit
Method of measurement
Spectrophotometer device

Secondary outcomes

1

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
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Sponsors / Funding sources

1

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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
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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