Clinical Trial Protocol
Iranian Registry of Clinical Trials

08 Jun 2026

Effect of fresh frozen plasma for priming cardiopulmonary bypass machine on rotational thromboelastometry (Rotem) parameters and received blood products in children undergoing cardiac surgery

Protocol summary

Summary

The aim of the study is to examine the effect of fresh frozen plasma (FFP) for priming cardiopulmonary bypass machine on rotationa thromboelastometry (Rotem) parameters and received blood products in children undergoing cardiac surgery. In this randomized controlled trial, children undergoing open heart surgery will be randomely allocated to experimental or control group. Inclusion criteria will be negative history of sternotomy, coagulopathy and liver dysfunction. Exclusion criteria will include patients death, giving up the cooperation by patient or the family and receiving blood products during the last 24 hrs. In the experimental group, FFP and crystalloid solution (Ringer) and in the control group, Hydroxyethyl Starch and crystalloid solution (Ringer) will be used as priming solution for cardiopulmonary bypass pump. Rotem parameters will be measured two times, before anesthesia induction and 10 minutes after protamine injection. Rotem parameters and the volume of received blood products will be compared between the groups using statistical tests.

General information

Acronym

IRCT registration information

IRCT registration number: **IRCT2016101313785N3**
Registration date: **2016-12-30, 1395/10/10**
Registration timing: **registered_while_recruiting**

Last update:
Update count: **0**

Registration date

2016-12-30, 1395/10/10

Registrant information

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Recruitment status

Recruitment complete

Funding source
Vice Chancellor for Research, Iran University of Medical Sciences

Expected recruitment start date

2016-04-03, 1395/01/15

Expected recruitment end date

2017-01-04, 1395/10/15

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Effect of fresh frozen plasma for priming cardiopulmonary bypass machine on rotational thromboelastometry (Rotem) parameters and received blood products in children undergoing cardiac surgery

Public title

The effect of fresh frozen plasma on rotational thromboelastometry (Rotem) parameters and received blood products in children under cardiac surgery

Purpose

Prevention

Inclusion/Exclusion criteria
Inclusion Criteria: No history of sternotomy; No coagulopathy; No hepatic diasese Exclusion Criteria: Dying patient; Giving up participation in the study; blood or blood products transfusion within the last 24 hrs
Age
No age limit
Gender
Both

Phase
N/A
Groups that have been masked
No information
Sample size
Target sample size: **84**
Randomization (investigator's opinion)
Randomized
Randomization description
Blinding (investigator's opinion)
Double blinded
Blinding description
Placebo
Not used
Assignment
Parallel
Other design features
Random allocation by random number table

Secondary Ids

empty

Ethics committees

1

Ethics committee
Name of ethics committee
Ethics Committee of Iran University of Medical Sciences
Street address
Sheikhfazlollah and Hemmat expertways crossover
City
Tehran
Postal code
Approval date
2016-03-07, 1394/12/17
Ethics committee reference number
IR.IUMS.REC 1394.9211584202

Health conditions studied

1

Description of health condition studied
Cardiovascular Disease
ICD-10 code
Q28-9
ICD-10 code description
Congenital malformation of circulatory system, unspecified

Primary outcomes

1

Description
Rotem parameters
Timepoint
before anesthesia induction and after weaning from cardiopulmonary bypass machine
Method of measurement
Rotem measurement system

Secondary outcomes

1

Description
Received boold products
Timepoint
during operation and 24hrs after surgery
Method of measurement
Milliliter

Intervention groups

1

Description
Intervention group: o̎r every kg of body weight, 10-20 ml fresh frozen plasma (FFP) and 100-200 ml crystalloid solution (Ringer dolurion) will be used as priming solution. To maintain hematocrit at 20 percent, all patients will receive packed cell. remaining of the cardiovascular bypass process would be the same for both groups. After surgery, to alleviate the effect of heparin, 1 mg Protamin/ kg body weight will be injected and then the patient will be weaned from bypass machine.
Category
Prevention

2

Description
Control group: For every kg of body weight, 10-20 ml hydroxyethyl starch with proportion of 130 to 0.4 and 100-200 ml crystalloid solution (Ringer dolurion) will be used as priming solution. To maintain hematocrit at 20 percent, all patients will receive packed cell. Remaining of the cardiovascular bypass process would be the same for both groups. After surgery, to alleviate the effect of heparin, 1 mg Protamin/ kg body weight will be injected and then the patient will be weaned from bypass machine.
Category
Prevention

Recruitment centers

1

Recruitment center

Name of recruitment center
Rajaei Cardiovascular, Medical and Research Center

Full name of responsible person
Dr. Hamid Peyrovi

Street address
School of Nursing and Midwifery, Rashid Yasami St., Vali-Asr Ave

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Tehran

Sponsors / Funding sources

1

Sponsor

Name of organization / entity
Vice Chancellor of research of Iran University of Medical Sciences

Full name of responsible person
Dr. Naserbakht

Street address
Research director of Iran University of Medical Sciences

City
Tehran

Grant name

Grant code / Reference number

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

Title of funding source
Vice Chancellor of research of Iran University of Medical Sciences

Proportion provided by this source
100

Public or private sector
empty

Domestic or foreign origin
empty

Category of foreign source of funding
empty

Country of origin

Type of organization providing the funding
empty

Person responsible for general inquiries

Contact

Name of organization / entity
Iran University of Medical Sciences

Full name of responsible person
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Position
Ph.D in Nursing, Faculty member

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Sharing plan

Deidentified Individual Participant Data Set (IPD)
empty

Study Protocol

empty

Statistical Analysis Plan

empty

Informed Consent Form

empty

Clinical Study Report

empty

Analytic Code

empty

Data Dictionary

empty