

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 rotational thromboelastometry (Rotem) parameters and received blood products in children undergoing cardiac surgery. In this randomized controlled trial, children undergoing open heart surgery will be randomly 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

Name

Hamid Peyrovi

Name of organization / entity

Tehran University of Medical Sciences

Country

Iran (Islamic Republic of)

Phone

+98 21 6105 4404

Email address

h-peyrovi@tums.ac.ir

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 disease 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 blood products

Timepoint

during operation and 24hrs after surgery

Method of measurement

Milliliter

Intervention groups

1

Description

Intervention group: for 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

City

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

Dr. Hamid Peyrovi

Position

Ph.D in Nursing, Faculty member

Other areas of specialty/work

Street address

Vali-Asr Ave, After Vanak Sq, Rashid Yasami St., school
of Nursing and Midwifery

City

Tehran

Postal code

Phone

+98 21 4365 1705

Fax

Email

hamidpeyravi@yahoo.com

Web page address

Person responsible for scientific inquiries

Contact

Name of organization / entity

Iran University of Medical Sciences

Full name of responsible person

Dr. Hamid Peyrovi

Position

Ph.D in Nursing

Other areas of specialty/work

Street address

Vali-Asr Ave, After Vanak Sq, Rashid Yasami St., school
of Nursing and Midwifery

City

Tehran

Postal code

Phone

+98 21 4365 1705

Fax

Email

hamidpeyravi@yahoo.com

Web page address

Person responsible for updating data

Contact

Name of organization / entity

School of Nursing and Midwifery, Iran University of
Medical Sciences

Full name of responsible person

Dr. Hamid Peyrovi

Position

PhD of Nursing/ faculty Member

Other areas of specialty/work

Street address

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

City

Tehran

Postal code

Phone

+98 21 4365 1705

Fax

Email

hamidpeyravi@yahoo.com

Web page address

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