

Clinical Trial Protocol

Iranian Registry of Clinical Trials

19 Sep 2026

Comparison of the Effectiveness of Thromboelastometry -Based Blood Management with Conventional Management in Blood and Blood Components Consumption in Patients Undergoing Combined Coronary-Valve Surgery

Protocol summary

Study aim

Evaluation of the management of transfusion using thromboelastometry test in blood and blood product consumption

Design

Two arm parallel group randomized trial design of 80 patients; double blinded

Settings and conduct

Rajaie Cardiovascular Medical and Research Center

Participants/Inclusion and exclusion criteria

Inclusion criteria: Patients scheduled for combined coronary- valve surgery Exclusion criteria: Patients with hereditary coagulopathy; Liver dysfunction; renal dysfunction; and redo surgery

Intervention groups

Rotem group: In this group transfusion conduct based on the thromboelastometry test results Control group: In this group transfusion conduct based on the conventional coagulation tests results

Main outcome variables

Number of transfused RBC, Platelet and FFP units; Number of patients who transfused

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20170705034908N2**

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

Elham Khalaf Adeli

Name of organization / entity

High Institute for Education and Research in Transfusion Medicine,

Country

Iran (Islamic Republic of)

Phone

+98 88601582

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adeli.elham@gmail.com

Recruitment status

Recruitment complete

Funding source

High Institute for Education and Research in Transfusion Medicine,, Rajaie cardiovascular medical and research center

Expected recruitment start date

2016-04-20, 1395/02/01

Expected recruitment end date

2017-08-22, 1396/05/31

Actual recruitment start date

2016-04-20, 1395/02/01

Actual recruitment end date

2017-08-22, 1396/05/31

Trial completion date

empty

Scientific title

Comparison of the Effectiveness of Thromboelastometry -Based Blood Management with Conventional Management in Blood and Blood Components Consumption in Patients Undergoing Combined Coronary- Valve Surgery

Public title

Effects of Thromboelastometry-Based blood management on transfusion in cardiac surgery

Purpose

Prevention

Inclusion/Exclusion criteria**Inclusion criteria:**

Adult patients scheduled for elective combined coronary-valves surgery with CPB Patients who have minimum hemoglobin 8 g/dl and Hematocrit 24, before surgery Patients who have discontinued the anti-platelet drugs at least 5 days and Warfarin at least 3 days before surgery

Exclusion criteria:

Patients with hereditary coagulopathy Patients with severe liver dysfunction Patients with renal dysfunction Patients with Redo surgery Patients who are pregnant Patients who are requiring emergency surgery

Age

From **18 years** old to **75 years** old

Gender

Both

Phase

N/A

Groups that have been masked

- Participant
- Outcome assessor

Sample size

Target sample size: **80**

Actual sample size reached: **80**

Randomization (investigator's opinion)

Randomized

Randomization description

Study population will randomize to two groups using a computer generated randomization list. The method of randomization is balanced block .

Blinding (investigator's opinion)

Double blinded

Blinding description

Both participants and people who collect the data are blind about intervention groups

Placebo

Not used

Assignment

Parallel

Other design features**Secondary Ids**

empty

Ethics committees**1****Ethics committee****Name of ethics committee**

Ethics committee of High Institute for Education and Research in Transfusion Medicine,

Street address

IBTO; Hemmat EXPY; Adjacent to Milad Tower

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Tehran

Province

Tehran

Postal code

1157-14665

Approval date

2016-04-09, 1395/01/21

Ethics committee reference number

IR.TMI.REC.1393.14

Health conditions studied**1****Description of health condition studied**

Coronary-Valve surgery

ICD-10 code

197.1

ICD-10 code description

Other functional disturbances following cardiac surgery

Primary outcomes**1****Description**

Number of transfused units of RBC, FFP, and Platelet

Timepoint

During surgery and 24 hours after surgery

Method of measurement

Count of the number of consumed bags

2**Description**

Frequency of patients who transfused

Timepoint

During surgery and 24 hours after surgery

Method of measurement

Count of transfused patients using checklist

Secondary outcomes

empty

Intervention groups**1****Description**

First intervention group: Thromboelastometry tests including(Extem , Intem, Heptem,Fibtem) will be performed in two time point (before and after CPB) . Transfusion will be directed using a protocol based on the results of the thromboelastometry tests

Category

Other

2**Description**

Control group: Patients will be transfused according to the routine practices in this center including conventional coagulation testing(PT, PTT, INR, fibrinogen, Platelet count) and clinical decision

Category

Other

Recruitment centers

1

Recruitment center

Name of recruitment center

Rajaie Cardiovascular Medical and Research Center

Full name of responsible person

Elham Khalaf-Adeli

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Mellat park, Vali-Asr Avenue,Tehran,Iran

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Sponsors / Funding sources

1

Sponsor

Name of organization / entity

High Institute for Education and Research in Transfusion Medicine,

Full name of responsible person

Ali Akbar Pourfathollah

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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

High Institute for Education and Research in Transfusion Medicine,

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

Iranian Blood Transfusion Organization

Full name of responsible person

Ali Akbar Pourfathollah

Position

Ibto manager, Professor

Latest degree

Ph.D.

Other areas of specialty/work

Hematology, Transfusion medicine

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Web page address

Person responsible for scientific inquiries

Contact

Name of organization / entity

High Institute for Education and Research in Transfusion Medicine,

Full name of responsible person

Elham Khalaf Adeli

Position

Assistant professor

Latest degree

Ph.D.

Other areas of specialty/work

Transfusion medicine

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Position

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Latest degree

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Other areas of specialty/work

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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

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

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

Not applicable