

Clinical Trial Protocol

Iranian Registry of Clinical Trials

09 Jun 2026

Studying effect of tranexamic acid plus fibrinogen on mediastinal bleeding in cardiac patients after open heart surgery

Protocol summary

Summary

Aim: The present study is a comparative analysis of the effect of tranexamic acid with fibrinogen on mediastinal bleeding after cardiac surgery. After undergoing cardiac surgery, patients with more than 200 cc/hour mediastinal bleeding are randomly divided into control and intervention groups (according to the random number table). The data related to the first group (control group) that received only 15mg/kg tranexamic acid are collected using a questionnaire. The subjects in the intervention group are injected with 15mg/kg (milligrams per kilogram) tranexamic acid plus 2g fibrinogen. Then, the length of stay in the intensive care unit (ICU), mediastinal drainage, use of blood products, intubation time in ICU, discharge conditions and mortality are registered for each subject. 40 subjects are allocated to each group. The patients who meet the following criteria are included in the study: 1) Mediastinal drainage of more than 200 cc/hour after cardiac surgery, 2) Age < 70 years, 3) Ejection Fraction (EF) > 30% and 4) Body Mass Index (BMI) < 30. The exclusion criteria are as follows: 1) Emergency or second cardiac surgery, 2) Hemoglobin (Hb) < 10, 3) Platelet count < 100,000/cc and 4) Hematologic diseases. The present study is double blind, meaning that the patient and the person who fills out the questionnaire are not informed about the prescribed/unprescribed drugs.

General information

Acronym

IRCT registration information

IRCT registration number: **IRCT2013082714489N1**
Registration date: **2014-04-07, 1393/01/18**
Registration timing: **registered_while_recruiting**

Last update:

Update count: **0**

Registration date

2014-04-07, 1393/01/18

Registrant information

Name

Mohammad Esmaeelzadeh

Name of organization / entity

Mashhad university of medical sciences

Country

Iran (Islamic Republic of)

Phone

+98 51 1802 2022

Email address

esmaeelzadehm901@mums.ac.ir

Recruitment status

Recruitment complete

Funding source

Doctor Shahram Amini

Expected recruitment start date

2013-11-22, 1392/09/01

Expected recruitment end date

2014-07-06, 1393/04/15

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Studying effect of tranexamic acid plus fibrinogen on mediastinal bleeding in cardiac patients after open heart surgery

Public title

Effect of fibrinogen on bleeding after cardiac surgery

Purpose

Treatment

Inclusion/Exclusion criteria

Inclusion criteria: 1) Mediastinal drainage of more than

200 cc/hour after cardiac surgery, 2) Age<70 years, 3) Ejection Fraction (EF)>30% and 4) Body Mass Index (BMI)<30; Exclusion criteria: 1) Emergency or second cardiac surgery, 2) Hemoglobin (Hb)<10, 3) platelet count<100,000/cc, and 4) Hematologic diseases

Age

From **15 years** old to **70 years** old

Gender

Both

Phase

N/A

Groups that have been masked

No information

Sample size

Target sample size: **80**

Randomization (investigator's opinion)

Randomized

Randomization description

Blinding (investigator's opinion)

Double blinded

Blinding description

Placebo

Not used

Assignment

Parallel

Other design features

The subjects are divided into control and intervention groups according to random number table.

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee

Ethics committee of Mashhad university of medical sciences

Street address

Central building of Mashhad university of medical sciences, after Shahid Javan square, Shahid Fakoori street

City

Mashhad

Postal code

Approval date

2013-02-07, 1391/11/19

Ethics committee reference number

910249

Health conditions studied

1

Description of health condition studied

Ischemic heart diseases

ICD-10 code

I20.9

ICD-10 code description

Angina pectoris, unspecified

2

Description of health condition studied

Nonrheumatic mitral valve disorders

ICD-10 code

I34.9

ICD-10 code description

Nonrheumatic mitral valve disorders, unspecified

3

Description of health condition studied

Nonrheumatic aortic valve disorders

ICD-10 code

I35.9

ICD-10 code description

Nonrheumatic aortic valve disorders, unspecified

4

Description of health condition studied

Nonrheumatic tricuspid valve disorders

ICD-10 code

I36.9

ICD-10 code description

Nonrheumatic tricuspid valve disorders, unspecified

5

Description of health condition studied

Pulmonary valve disorders

ICD-10 code

I37.9

ICD-10 code description

Pulmonary valve disorders, unspecified

6

Description of health condition studied

Rheumatic heart diseases

ICD-10 code

I01.9

ICD-10 code description

Acute rheumatic heart disease, unspecified

Primary outcomes

1

Description

Mediastinal bleeding

Timepoint

Conducted on an hourly basis for 48 hours from the time of ICU admission after surgery (before and after the intervention)

Method of measurement

Registered in the questionnaire (cc/hour)

Secondary outcomes

1

Description

Mortality

Timepoint

Measured daily during the hospital stay before and after the intervention

Method of measurement

Registered in the questionnaire according to patients percentage until discharge

2

Description

ICU length of stay

Timepoint

The length of post-operative ICU stay before and after the intervention

Method of measurement

Registered in the questionnaire on a daily basis

3

Description

Blood product usage (fresh frozen plasma, platelets, packed cells, whole blood)

Timepoint

Registered every 4 hours for a 48 hours period, during the post-operative ICU stay (before and after the intervention)

Method of measurement

Registered in the questionnaire according to the products bag

Intervention groups

1

Description

The subjects in the intervention group are injected with 15mg/kg tranexamic acid plus 2 g(grams) fibrinogen (Haemocomplettan as the generic name). Afterwards, the length of stay in the ICU, mediastinal bleeding, use of blood products, intubation time in ICU, discharge conditions and mortality are registered for each subject. These drugs are intravenously injected in one session, immediately after mediastinal bleeding of more than 200 cc/hr. The last stage in non-responder patients is re-exploration.

Category

Treatment - Drugs

2

Description

The second group consists of control subjects who receive 15 mg/kg tranexamic acid and routine care (including blood pressure control and use of blood products according to the paraclinical findings). The last stage in non-responder patients is re-exploration.

Category

Treatment - Drugs

Recruitment centers

1

Recruitment center

Name of recruitment center

Emam Reza hospital

Full name of responsible person

Doctor Mohammad Esmaeelzadeh

Street address

Emam Reza square, Ebne Sina street

City

Mashhad

Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Vice chancellor for research, Mashhad university of medical sciences

Full name of responsible person

Doctor Mohsen Tafaghodi

Street address

Ghoreishi building, Daneshgah street

City

Mashhad

Grant name

Grant code / Reference number

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

Yes

Title of funding source

Vice chancellor for research, Mashhad 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

Mashhad university of medical sciences

Full name of responsible person

Doctor Mohammad Esmaeelzadeh

Position

Resident of anesthesiology and ICU

Other areas of specialty/work

Street address

Emam Reza hospital, Emam Reza square, Ebne sina street

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Person responsible for scientific inquiries

Contact

Name of organization / entity

Mashhad university of medical sciences

Full name of responsible person

Doctor Shahram Amini

Position

ICU fellowship, anesthesiologist

Other areas of specialty/work

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Person responsible for updating data

Contact

Name of organization / entity

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Full name of responsible person

Doctor Mohammad Esmaeelzadeh

Position

Resident of anesthesiology and ICU

Other areas of specialty/work

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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