Clinical Trial Protocol
Iranian Registry of Clinical Trials

17 Sep 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

City

Mashhad

Postal code

Phone

+98 51 1802 2314

Fax

Email

Esmaeilzm901@mums.ac.ir

Web page address

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

Street address

Emam Reza hospital, Emam Reza square, Ebne Sina street

City

Mashhad

Postal code

Phone

+98 51 1802 2314

Fax

Email

Aminish@mums.ac.ir

Web page address

Person responsible for updating data

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

City

Mashhad

Postal code

Phone

+98 51 1802 2314

Fax

Email

Esmaeilzm901@mums.ac.ir

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