

Clinical Trial Protocol

Iranian Registry of Clinical Trials

03 Jul 2026

Comparison of pre- and post cardiopulmonary bypass tranexamic acid effect on the amount of bleeding after coronary artery bypass graft surgery

Protocol summary

Summary

The purpose of our study is to compare pre and post cardiopulmonary bypass tranexamic acid effect on the bleeding after coronary artery bypass graft surgery, Randomised clinical trial. In this study the researcher, the research assistant, and the participants will be blind. Bleeding due to coagulopathy after CPB (Cardio-pulmonary bypass) may cause complications and mortality. There are a lot of causes to this coagulopathy like fibrinolytic activity. Tranexamic acid (TA) leads to complex formation with plasmin and plasminogen, which prevents them from binding to fibrin. Many studies have confirmed the effect of TA in reducing post-surgical bleeding. We intend to design a clinical trial using the idea of preemptive measures on causing complications over the body, to compare the effect of TA before and after CPB on amount of bleeding after cardiac surgery. Sixty patients who are candidates for CABG, after filling out informed consent forms, were divided into 2 groups, randomly. Before surgical incision, group 1 patients had a TA injection and patients in group 2 were injected by normal saline. After getting off the CPB, first group received normal saline and second one TA. The amount of bleeding after surgery was measured by the blood accumulated inside the chest bottle and the transfused blood units after surgery were recorded. Our main outcome variables are the amount of bleeding.

General information

Acronym

Tranexamic acid effect

IRCT registration information

IRCT registration number: **IRCT2015090723933N1**

Registration date: **2015-09-18, 1394/06/27**

Registration timing: **registered_while_recruiting**

Last update:

Update count: **0**

Registration date

2015-09-18, 1394/06/27

Registrant information

Name

Sohrab Negargar

Name of organization / entity

Tabriz University of Medical Sciences

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Recruitment status

Recruitment complete

Funding source

Tabriz University Of Medical Sciences

Expected recruitment start date

2015-03-20, 1393/12/29

Expected recruitment end date

2016-01-19, 1394/10/29

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Comparison of pre- and post cardiopulmonary bypass tranexamic acid effect on the amount of bleeding after coronary artery bypass graft surgery

Public title

Comparison of pre- and post cardiopulmonary bypass

tranexamic acid effect on the amount of bleeding after coronary artery bypass graft surgery

Purpose

Prevention

Inclusion/Exclusion criteria

inclusion criteria: Patients under 75 years old candidate for cardiopulmonary Artery Bypass Graft surgery in the operation room of Tabriz Shahid Madani Hospital.

Exclusion criteria: Emergency surgery; Coagulopathy problems like Hemophilia, platelet below 100000 per ml, PT and PTT 1.5 times above normal range; Renal failure (Serum creatinine over 2mg/dl); Allergy to Tranexamic acid; Existence of thrombotic state (Subarachnoid Hemorrhage, gallbladder disease, Vein thrombosis, Emboli); Plavix (Clopidogrel) consumption during 7 days before operation; Streptokinase consumption during 48 hours before operation; Patients with poor heart contraction power (EF<35%); Aspirin consumption with high dose during 48 hours before operation; Repeated heart surgery operation (Redo); Active liver disease; Patients with Hb<10 g/dl

Age

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

Gender

Both

Phase

N/A

Groups that have been masked

No information

Sample size

Target sample size: **60**

Randomization (investigator's opinion)

Randomized

Randomization description

Blinding (investigator's opinion)

Double blinded

Blinding description

Placebo

Not used

Assignment

Parallel

Other design features

Explained in summary

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee

Ethics committee of Tabriz University of Medical Sciences

Street address

Daneshgah Avenue

City

Tabriz

Postal code

5166615573

Approval date

2014-03-10, 1392/12/19

Ethics committee reference number

TBZMED-REC 9337

Health conditions studied

1

Description of health condition studied

Amount of bleeding in Coronary Artery Bypass Graft Surgery

ICD-10 code

I24

ICD-10 code description

Other acute ischaemic heart diseases

Primary outcomes

1

Description

Amount of bleeding

Timepoint

During operation upto discharge

Method of measurement

Amount of bleeding from chest bottle per ml

Secondary outcomes

empty

Intervention groups

1

Description

Intervention: 20mg/kg Tranexamic acid before surgical incision

Category

Prevention

2

Description

Control: 20mg/kg Tranexamic acid 10 minutes after getting Cardiopulmonary bypass

Category

Prevention

Recruitment centers

1

Recruitment center

Name of recruitment center

Shahid Madani Heart Hospital, Tabriz Department of Anesthesiology, Tabriz University of Medical Sciences

Full name of responsible person

Sohrab Negargar, Professor of Anesthesiology

Street address

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Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Tabriz University Of Medical Sciences

Full name of responsible person

Dr Sohrab Negargar

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City

Tabriz

Grant name

Grant code / Reference number

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

Yes

Title of funding source

Tabriz 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

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Full name of responsible person

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Position

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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