Clinical Trial Protocol
Iranian Registry of Clinical Trials

19 Sep 2026

Does topical application of transexamic acid reduce postoperative bleeding in coronary artery bypass graft surgery?

Protocol summary

Summary

Postoperative bleeding is a common problem in cardiac surgery. We try to evaluate the effect of topical tranexamic acid (TA) on reducing postoperative bleeding of patients undergoing on pump coronary artery bypass graft (CABG) surgery. 120 isolated primary CABG patients will be included in the study. They will be divided blindly into two groups; group 1, patients receiving 1 gram TA diluted in 50 cc normal saline poured into mediastinal cavity before closing the chest and group 2 (control), patients receiving 50 ml normal saline at the end of operation. First 24 and 48 hours chest tube drainage, hemoglobin decrease and packed RBC transfusion needs will be compared.

General information

Acronym

-

IRCT registration information

IRCT registration number: **IRCT2016071628945N1**
Registration date: **2016-10-22, 1395/08/01**
Registration timing: **prospective**

Last update:
Update count: **0**

Registration date

2016-10-22, 1395/08/01

Registrant information

Name

Amir Mirmohammadsadeghi

Name of organization / entity

Isfahan Univesity of Medical Sciences

Country

Iran (Islamic Republic of)

Phone

+98 31 3260 0961

Email address

am_sadeghi@med.mui.ac.ir

Recruitment status

Recruitment complete

Funding source

Sina Hospital, Isfahan, Iran

Expected recruitment start date

2016-11-01, 1395/08/11

Expected recruitment end date

2017-11-01, 1396/08/10

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Does topical application of transexamic acid reduce postoperative bleeding in coronary artery bypass graft surgery?

Public title

Does topical application of transexamic acid reduce postoperative bleeding in coronary artery bypass graft surgery?

Purpose

Treatment

Inclusion/Exclusion criteria

Inclusion criteria: patients undergoing CABG surgery alone; interrupting aspirin three days and Plavix at least five days before surgery; lack of consuming any other anticoagulant drugs such as heparin or warfarin; lack of coagulation and bleeding disorders; lack of liver and kidney disease; Ejection fraction> 35%. Exclusion criteria: complex surgery; emergency surgery; anticoagulation therapy before surgery; having hemoglobin lower than 8 grams per deciliter before surgery.

Age

From **20 years** old to **90 years** old

Gender

Both

Phase

4

Groups that have been masked

No information

Sample size

Target sample size: **120**

Randomization (investigator's opinion)

Randomized

Randomization description

Blinding (investigator's opinion)

Double blinded

Blinding description

Placebo

Used

Assignment

Parallel

Other design features

randomization will be done by even and odd registration number.

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee

Isfahan University of Medical Sciences

Street address

Darvaze shiraz- hezar jerib street

City

Isfahan

Postal code

Approval date

2016-04-23, 1395/02/04

Ethics committee reference number

IR.MUI.REC.1395.4.13

Health conditions studied

1

Description of health condition studied

bleeding

ICD-10 code

I97.8

ICD-10 code description

Other postprocedural disorders of circulatory system, not elsewhere classified

Primary outcomes

1

Description

postoperative bleeding

Timepoint

24 hrs and 48 hrs postoperatively

Method of measurement

drainage in chest tube

Secondary outcomes

empty

Intervention groups

1

Description

Intervention group: patients receiving 1 gram TA diluted in 50 cc normal saline poured into mediastinal cavity before closing the chest

Category

Treatment - Drugs

2

Description

Control group: patients receiving 50 ml normal saline poured into mediastinal cavity before closing the chest

Category

Treatment - Drugs

Recruitment centers

1

Recruitment center

Name of recruitment center

Sina Hospital

Full name of responsible person

Amir Mirmohammadsadeghi

Street address

Sina Hospital, Shamsabadi, Isfahan, Iran

City

Isfahan

Sponsors / Funding sources

1

Sponsor

Name of organization / entity

investigator

Full name of responsible person

investigator

Street address

-

City

-

Grant name

Grant code / Reference number

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

Yes

Title of funding source

investigator

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

Isfahan University of Medical Sciences

Full name of responsible person

Amir Mirmohammadsadeghi

Position

Assistant professor

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