

Clinical Trial Protocol

Iranian Registry of Clinical Trials

10 Jun 2026

: A Study on the Effect of 2g Vancomycin paste with 200mg Tranexamic acid Ampoule Compared to Vancomycin with Distilled Water in Reducing Bleeding Amount After Coronary Bypass Surgery

Protocol summary

Study aim

Determination of the effect of dough made of 2 g vancomycin with 200 mg tranexamic acid ampoule compared to vancomycin with distilled water in reducing bleeding after coronary artery bypass graft surgery

Design

Patients were randomly divided into two control and intervention groups (n = 50); phase 3; clinical trial.

Settings and conduct

The study was performed in Chamran hospital of Isfahan. Vancomycin paste was used on the sternum bone in intervention group after open heart surgery. Postoperative bleeding was measured.

Participants/Inclusion and exclusion criteria

Inclusion criteria: 35 to 80 years of age, elective CABG surgery, and patient satisfaction to participate in the study. Exclusion criteria: coagulation disorder (platelet less than 100,000), receiving heparin and other anticoagulants 48 hours before surgery, taking antiplatelet drugs 5 days before surgery, history of taking non-steroid anti-inflammatory drugs within 3 days before the operation, And those with a history of renal failure and thrombosis

Intervention groups

Before sternum closure, vancomycin + tranexamic paste was applied to the sternum bone (in the intervention group) and vancomycin + normal saline paste to the sternum bone (control group).

Main outcome variables

Volume of bleeding; Volume of injected blood products

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20190714044205N1**

Registration date: **2020-02-18, 1398/11/29**

Registration timing: **retrospective**

Last update: **2020-02-18, 1398/11/29**

Update count: **0**

Registration date

2020-02-18, 1398/11/29

Registrant information

Name

Hafez Asadolahi

Name of organization / entity

Country

Iran (Islamic Republic of)

Phone

+98 31 3261 6613

Email address

hafez.perfusion96@gmail.com

Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2019-06-22, 1398/04/01

Expected recruitment end date

2019-09-21, 1398/06/30

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

: A Study on the Effect of 2g Vancomycin paste with 200mg Tranexamic acid Ampoule Compared to Vancomycin with Distilled Water in Reducing Bleeding Amount After Coronary Bypass Surgery

Public title

effect of tranexamic acid in reducing bleeding after coronary bypass surgery

Purpose

Treatment

Inclusion/Exclusion criteria**Inclusion criteria:**

selective CABG surgery Patient satisfaction to participate in the study

Exclusion criteria:

coagulation disorder receive heparin and other anticoagulants 48 hours before surgery history of renal failure and thrombosis taking antiplatelet drugs within 5 days before surgery

Age

From **35 years** old to **80 years** old

Gender

Both

Phase

3

Groups that have been masked

- Care provider
- Outcome assessor

Sample size

Target sample size: **50**

Randomization (investigator's opinion)

Randomized

Randomization description

Using random allocation software and simple randomization method, 50 eligible patients were assigned into two groups of 25 (control group (vancomycin + normal saline) and intervention group (vancomycin + tranexamic acid). Random assignment by counseling The project statistic was done and finally the codes produced were given by the surgeon assistant who was responsible for the composition of the drugs. The surgeon and the outcome evaluator after surgery only had access to the codes.

Blinding (investigator's opinion)

Double blinded

Blinding description

After preparation of vancomycin paste made with tranexamic acid or normal saline, the paste was given to the surgeon without any information about the content. Paste was used by the surgeon on the sternum bone and the data were collected by an evaluator without any information about the type of paste.

Placebo

Not used

Assignment

Parallel

Other design features**Secondary Ids**

empty

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

Ethics Committee of Isfahan University of Medical Sciences

Street address

West Tulip Blvd Koi Alikhani Mother Apartment

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esfahan

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Isfahan

Postal code

8158988994

Approval date

2019-07-13, 1398/04/22

Ethics committee reference number

ir.mui.med.rec.1398.187

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

Bleeding after open heart surgery

ICD-10 code**ICD-10 code description****Primary outcomes****1****Description**

Bleeding

Timepoint

12-24-48 hours after surgery

Method of measurement

Via chest Buttel in icu section

Secondary outcomes

empty

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

Intervention group: In the intervention group, a vancomycin 2g paste with 200 mg tranexamic acid ampoule was applied to the sternum bone.

Category

Treatment - Drugs

2**Description**

Control group: Control group received two grams of vancomycin with normal saline.

Category

Treatment - Drugs

Recruitment centers

1

Recruitment center

Name of recruitment center

Chamran Hospital

Full name of responsible person

Hafez Asadollahi

Street address

Salman Fars Hospital, Chamran Hospital

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Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Esfahan University of Medical Sciences

Full name of responsible person

Assistant Director of Research and Technology at the University.

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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

Esfahan University of Medical Sciences

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

Esfahan University of Medical Sciences

Full name of responsible person

Hafez Asadollahi

Position

Nurse

Latest degree

Bachelor

Other areas of specialty/work

Nursery

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Person responsible for scientific inquiries

Contact

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Position

Assistant Professor

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Subspecialist

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Person responsible for updating data

Contact

Name of organization / entity

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Full name of responsible person

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Position

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Latest degree

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Sharing plan**Deidentified Individual Participant Data Set (IPD)**

Yes - There is a plan to make this available

Study Protocol

Yes - There is a plan to make this available

Statistical Analysis Plan

Yes - There is a plan to make this available

Informed Consent Form

Yes - There is a plan to make this available

Clinical Study Report

Yes - There is a plan to make this available

Analytic Code

Yes - There is a plan to make this available

Data Dictionary

Yes - There is a plan to make this available

Title and more details about the data/document

The first 12 hours after the first 24 hours after the operation, the first 48 hours after the operation

When the data will become available and for how long

1399

To whom data/document is available

all

Under which criteria data/document could be used

all

From where data/document is obtainable

09120643032

What processes are involved for a request to access data/document

After a month

Comments