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

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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
Province
Isfehan
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
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Sponsors / Funding sources

1

Sponsor

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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

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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