Clinical Trial Protocol
Iranian Registry of Clinical Trials

17 Sep 2026

study of effect of local Tranexamic acid in reducing postoperative bleeding on coronary artery bypass graft

Protocol summary

Study aim
study of effect of local Tranexamic acid in reducing postoperative bleeding on coronary artery bypass graft

Design
This study is clinical trial and double blind. 62 patients with arterial coronary artery bypass graft referring to Amiralmomenin Arak Hospital.We divide patients in two groups randomly.

Settings and conduct
This study is clinical trial and double blind. 62 patients with arterial coronary artery bypass graft referring to Amiralmomenin Arak Hospital.We divide patients in two groups randomly.

Participants/Inclusion and exclusion criteria
Inclusion criteria: Patients with elective CABG referrals; ASA Class 2 and 3; Tranexamic acid insensitivity; surgery performed by a surgeon; duration of surgery 4 to 6 hours Exclusion criteria: Increase the duration of the operation for more than 6 hours; cardiomegaly and CHF; going on a cardio-pulmonary pump for 2 times during operation; all patients who die during surgery; history of cardiac arrest and CPR before surgery

Intervention groups
En Intervention group: Before the separation of the pulmonary pump, patients are treated with 2 gram of Tranexamic acid in 100 milliliter and placed in the topical mediastinum of the patient by the surgeon.

Main outcome variables
We check bleeding afetr surgery, average number of Paccell received during 24 hours after surgery, average number of unit platelets received within 24 hours after surgery, average number of FFP units received within 24 hours of operation and average number of returns to the operating room to control bleeding within 24 hours of operation.

General information

Reason for update

Acronym

IRCT registration information
IRCT registration number: **IRCT20141209020258N62**
Registration date: **2018-01-17, 1396/10/27**
Registration timing: **registered_while_recruiting**

Last update: **2018-01-17, 1396/10/27**
Update count: **0**

Registration date
2018-01-17, 1396/10/27

Registrant information

Name
Fariba Farokhi

Name of organization / entity
Arak University of Medical Sciences

Country
Iran (Islamic Republic of)

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+98 86 3222 2003

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Recruitment status
Recruitment complete

Funding source

Expected recruitment start date
2017-11-11, 1396/08/20

Expected recruitment end date
2019-11-11, 1398/08/20

Actual recruitment start date
empty

Actual recruitment end date
empty

Trial completion date
empty

Scientific title
study of effect of local Tranexamic acid in reducing postoperative bleeding on coronary artery bypass graft

Public title
study of effect of local Tranexamic acid in reducing postoperative bleeding on coronary artery bypass graft
Purpose
Treatment
Inclusion/Exclusion criteria
Inclusion criteria:
Patients with elective CABG referrals ASA Class 2 and 3 Tranexamic acid insensitivity Surgery performed by a surgeon Duration of surgery 4 to 6 hours
Exclusion criteria:
Increase the duration of the operation for more than 6 hours cardiomegaly and CHF Going on a cardio-pulmonary pump for 2 times during operation All patients who die during surgery History of cardiac arrest and CPR before surgery
Age
No age limit
Gender
Both

Phase
2-3
Groups that have been masked

- Participant
- Data analyser

Sample size
Target sample size: **62**
Randomization (investigator's opinion)
Randomized
Randomization description
Randomization with random numbers
Blinding (investigator's opinion)
Double blinded
Blinding description
The patient is not aware of the treatment received.Participant and Analyzer are blind (double blind).
Placebo
Used
Assignment
Parallel
Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee
Name of ethics committee
Ethics committee Arak University Of Medical Sciences
Street address
Vice chancellor for research, Payambar azam complex, Basij squre, Sardasht, Arak
City
Arak
Province
Markazi
Postal code
3814957558
Approval date
2017-10-29, 1396/08/07
Ethics committee reference number
IR.ARAK.MU.REC.1396.156

Health conditions studied

1

Description of health condition studied
Coronary bypass graft
ICD-10 code
I25.70
ICD-10 code description
Atherosclerosis of coronary artery bypass graft(s), unspecified, with angina pectoris

Primary outcomes

1

Description
bleeding after surgery
Timepoint
after surgery
Method of measurement
score

2

Description
mean number of PACs received during 24 hours after surgery
Timepoint
24 hours after surgery
Method of measurement
count

3

Description
mean number of unit platelets received within 24 hours after surgery
Timepoint
24 hours after surgery
Method of measurement
count

4

Description
mean of number of FFP units received within 24 hours of surgery
Timepoint
24 hours after surgery
Method of measurement
count

5

Description
The average number of returns to the operating room to control bleeding within 24 hours of operation
Timepoint
24 hours after surgery
Method of measurement
count

Secondary outcomes

empty

Intervention groups

1

Description
Intervention group: Before the separation of the pulmonary pump, patients are treated with 2 gram of Tranexamic acid in 100 millileter and placed in the topical mediastinum of the patient by the surgeon.
Category
Treatment - Drugs

2

Description
Control group: Before the separation of the pulmonary pump, patients are treated with 100 millileter of normal saline and is topically injected into the mediastinum by the surgeon.
Category
Treatment - Drugs

Recruitment centers

1

Recruitment center
Name of recruitment center
Amiralmomenin hospital
Full name of responsible person
Dr Alireza Kamali
Street address
Amiralmomenin hospital, Sardasht
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Sponsors / Funding sources

1

Sponsor
Name of organization / entity
Arak University of Medical Sciences
Full name of responsible person
Dr Mohammad Arjmandzadegan
Street address
Vice chancellor for research, Payambar azam complex, Basij squre, Sardasht, Arak
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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
Arak 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
Arak University of Medical Sciences
Full name of responsible person
Dr Alireza rostami
Position
Assistant professor
Latest degree
Subspecialist
Other areas of specialty/work
Cardiology
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Person responsible for scientific inquiries

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Position

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Person responsible for updating data

Contact

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Full name of responsible person

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Position

medicine student

Latest degree

Medical doctor

Other areas of specialty/work

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Email

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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

When we publish article in journal.

When the data will become available and for how long

After the article is published

To whom data/document is available

researcher in university

Under which criteria data/document could be used

If there are additional questions

From where data/document is obtainable

Dr Alireza Kamali

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

They have to write letters to the professors and the university

Comments