

Clinical Trial Protocol

Iranian Registry of Clinical Trials

22 Jul 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 after 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)

Phone

+98 86 3222 2003

Email address

f.farokhi@arakmu.ac.ir

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 square, 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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alikalaliir@yahoo.com

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 squire, Sardasht, Arak

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arjmandzadegan@arakmu.ac.ir

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

Contact

Name of organization / entity

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Full name of responsible person

Dr Alireza Kamali

Position

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Person responsible for updating data

Contact

Name of organization / entity

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Amin Haji seyed hosseini

Position

medicine student

Latest degree

Medical doctor

Other areas of specialty/work

General Practitioner

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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