Clinical Trial Protocol
Iranian Registry of Clinical Trials

06 Jul 2026

Comparison of different doses of tranexamic acid on coronary perfusion in patients undergoing coronary artery bypass graft surgery (CABG)

Protocol summary

Study aim
Comparison of different doses of tranexamic acid on coronary perfusion

Design
Randomised, parallel group trial with blinded outcome assessment

Settings and conduct
Antifibrinolytics are common in cardiac surgeries. In some researches, higher doses of tranexamic acid have used for lowering of bleeding and transfusion. But in patients under CABG surgery, thrombosis and decreasing of perfusion in coronary arteries is a dangerous point. This trial will compare cardiac enzymes before and after CABG surgery in two different doses of tranexamic acid.

Participants/Inclusion and exclusion criteria
Inclusion: All patients under CABG surgery; EF> 40%; Age between 40 to 75 years Exclusion: Tranexamic acid sensitivity; Convulsion history; Thromboembolic event history

Intervention groups
Patients undergoing CABG surgery are randomly divided into two groups. After induction of anesthesia, the control group receive tranexamic acid at the usual dose of 10 mg/ kg plus infusion 2 mg/ kg/ h until the end of the operation and the intervention group receive a higher dose of 25 mg/ kg plus infusion 5 mg/ kg/ h until the end of the operation.

Main outcome variables
Cardiac enzymes, including Creatine kinase-MB and troponin , are measured before and after surgery in the usual dose and high-dose tranexamic acid groups. Significant increase in enzymes in the high dose group can be attributed to the thrombogenic effects of this dose.

General information

Reason for update

Acronym

IRCT registration information
IRCT registration number: **IRCT20180724040575N3**
Registration date: **2020-09-29, 1399/07/08**
Registration timing: **retrospective**

Last update: **2020-09-29, 1399/07/08**
Update count: **0**

Registration date
2020-09-29, 1399/07/08

Registrant information

Name
kamal fani

Name of organization / entity

Country
Iran (Islamic Republic of)

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+98 21 2207 4095

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kamalfani@sbmu.ac.ir

Recruitment status
Recruitment complete

Funding source

Expected recruitment start date
2018-08-23, 1397/06/01

Expected recruitment end date
2019-03-20, 1397/12/29

Actual recruitment start date
empty

Actual recruitment end date
empty

Trial completion date
empty

Scientific title
Comparison of different doses of tranexamic acid on coronary perfusion in patients undergoing coronary artery bypass graft surgery (CABG)

Public title
Effect of tranexamic acid on coronary perfusion
Purpose
Prevention
Inclusion/Exclusion criteria
Inclusion criteria:
Patients under CABG surgery Ejection Fraction(EF) >40%
Exclusion criteria:
Tranexamic acid sensitivity Convulsion history
Thromboembolic event history
Age
From **40 years** old to **75 years** old
Gender
Both

Phase
3
Groups that have been masked

- Participant
- Outcome assessor

Sample size
Target sample size: **120**
More than 1 sample in each individual
Number of samples in each individual: **2**
Cardiac enzymes before and after surgery
Randomization (investigator's opinion)
Randomized
Randomization description
All patients who go to the cardiac operating room from the beginning of sampling and meet the necessary criteria are included in the study. For assignment in intervention and control groups, simple randomization method is used with the help of random numbers(RAND) in Excel software. In cell A1, type the formula = RAND () * (120-1) +1. By confirming and dragging to A60, we have sixty random numbers between 1 and 120. These numbers are the rows of participants in the intervention group(high dose tranexamic acid). For each row of participants, a closed envelope is prepared by the researcher not present in the operating room, and with the arrival of each patient, the relevant envelope is opened by the project partner in the operating room and the designated group is determined
Blinding (investigator's opinion)
Double blinded
Blinding description
Consent for participation in the study is obtained from all patients, but the participants and data collector are blind about the study groups. The researcher and patient care team are aware of the groups.
Placebo
Not used
Assignment
Parallel
Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee
Name of ethics committee
Ethics committee of shahid beheshti University of Medical Sciences
Street address
Taleghani Hospital, Velenjak, Tehran, Iran
City
Tehran
Province
Tehran
Postal code
1996911151
Approval date
2018-03-20, 1396/12/29
Ethics committee reference number
IR.SBMU.RETECH.1396.720

Health conditions studied

1

Description of health condition studied
Coronary artery bypass graft surgery
ICD-10 code
ICD-10 code description

Primary outcomes

1

Description
Cardiac enzymes
Timepoint
Before and 24 hours after surgery
Method of measurement
Eliza method for cardiac enzymes measurment

Secondary outcomes

empty

Intervention groups

1

Description
Intervention group: Patients undergoing coronary artery bypass graft receiving a high dose of tranexamic acid. In this group, after induction of anesthesia, tranexamic acid drug made by Caspian Pharmaceutical Company (500 mg vial in 5 ml) at a dose of 25 mg / kg body weight by slow intravenous injection as a loading dose and then 5 mg / kg body weight It is given as an intravenous infusion as a maintenance dose until the end of the operation. Intravenous infusion is performed with the help of a pump syringe and the drug dissolved in a 50 ml syringe.
Category

Prevention

2

Description
Control group: Patients undergoing coronary artery bypass graft receiving a standard dose of tranexamic acid. In this group, after induction of anesthesia, tranexamic acid drug made by Caspian Pharmaceutical Company (500 mg in 5 ml) at a dose of 10 mg / kg body weight by slow intravenous injection as a loading dose and then 2 mg / kg body weight It is given as an intravenous infusion as a maintenance dose until the end of the operation. Intravenous infusion is performed with the help of a pump syringe and the drug dissolved in a 50 ml syringe.

Category
Prevention

Recruitment centers

1

Recruitment center

Name of recruitment center
Modarres Hospital
Full name of responsible person
Kamal Fani
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Sponsors / Funding sources

1

Sponsor

Name of organization / entity
Shahid Beheshti University of Medical Sciences
Full name of responsible person
Dr. Afshin Zarghi
Street address
Taleghani Hospital, Velenjak,Tehran, Iran
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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
Shahid Beheshti 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
Shahid Beheshti University of Medical Sciences
Full name of responsible person
Kamal Fani
Position
Assistant professor
Latest degree
Subspecialist
Other areas of specialty/work
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Person responsible for updating data

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Sharing plan

Deidentified Individual Participant Data Set (IPD)
Undecided - It is not yet known if there will be a plan to make this available

Study Protocol
Undecided - It is not yet known if there will be a plan to make this available

Statistical Analysis Plan
Undecided - It is not yet known if there will be a plan to make this available

Informed Consent Form
Undecided - It is not yet known if there will be a plan to make this available

Clinical Study Report
Undecided - It is not yet known if there will be a plan to make this available

Analytic Code
Undecided - It is not yet known if there will be a plan to make this available

Data Dictionary
Undecided - It is not yet known if there will be a plan to make this available