

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 been 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)

Phone

+98 21 2207 4095

Email address

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 measurement

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

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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

Anesthesiology

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Person responsible for scientific inquiries

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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