

Clinical Trial Protocol

Iranian Registry of Clinical Trials

05 Jul 2026

Investigating the effect of tranexamic acid injection on the postoperative chest drainage output of CABG patients compared to the control group

Protocol summary

Registration timing: **prospective**

Study aim

Investigating the effect of tranexamic acid injection on the postoperative chest drainage output of CABG patients compared to the control group

Last update: **2023-06-26, 1402/04/05**

Update count: **0**

Registration date

2023-06-26, 1402/04/05

Design

A clinical trial with a control group, with parallel and double-blind and randomized phase 4 groups will be conducted on 140 patients undergoing CABG. The website <https://www.Randomization.com> is used for random assignment. In order to hide random allocation, central randomization will be used.

Registrant information

Name

Nasim Sohrabifar

Name of organization / entity

Country

Iran (Islamic Republic of)

Phone

+98 938 229 6766

Email address

nasimsohrabifar@yahoo.com

Settings and conduct

The study will be conducted in the surgery department of Shahid Madras Hospital, Shahid Beheshti University of Medical Sciences. This study is done in a double blind way. Patients, caregivers, anesthesiologists, surgeons and operating room personnel are not informed about the type of study.

Recruitment status

Recruitment complete

Funding source

Participants/Inclusion and exclusion criteria

Entry criteria: - Age range 18-60 years - Patient consent
Non-entry criteria: Suffering from chronic kidney disease
- Use of anticoagulants

Expected recruitment start date

2023-07-23, 1402/05/01

Expected recruitment end date

2023-09-21, 1402/06/30

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Intervention groups

One gram of tranexamic acid will be injected before surgery to the intervention group, but not to the drug control group.

Main outcome variables

The amount of chest drainage of the patients after the operation will be the primary outcome and the transfusion during and after the operation will be the secondary outcome.

Scientific title

Investigating the effect of tranexamic acid injection on the postoperative chest drainage output of CABG patients compared to the control group

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20230626058586N1**

Registration date: **2023-06-26, 1402/04/05**

Public title

Investigating the effect of tranexamic acid on drainage output after CABG

Purpose

Treatment

Inclusion/Exclusion criteria

Inclusion criteria:

Age 18 to 60 years Informed consent Definite candidate for CABG

Exclusion criteria:

chronic kidney disease taking anticoagulants

Age

From **18 years** old to **60 years** old

Gender

Both

Phase

4

Groups that have been masked

- Participant
- Care provider
- Investigator
- Outcome assessor

Sample size

Target sample size: **140**

Randomization (investigator's opinion)

Randomized

Randomization description

The website <https://www.Randomization.com> is used for random assignment. In order to hide random allocation, central randomization will be used.

Blinding (investigator's opinion)

Double blinded

Blinding description

This study is done in a double blind way. Patients, caregivers, anesthesiologists, surgeons and operating room personnel are not informed about the type of study.

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

Cardiovascular Research Center, Saadat Abad Shahid Modares Hospital, Tehran

City

Tehran

Province

Tehran

Postal code

1998734383

Approval date

2023-06-26, 1402/04/05

Ethics committee reference number

IR.SBMU.MSP.REC.1401.424

Health conditions studied

1

Description of health condition studied

Coronary artery bypass grafting

ICD-10 code

T82.2

ICD-10 code description

Mechanical complication of coronary artery bypass graft and biological heart valve graft

Primary outcomes

1

Description

Examining drainage level after CABG surgery. It can be easily evaluated by drainage collection bag and will be calculated in cc.

Timepoint

After the surgery and for one week, the total level of drainage will be checked.

Method of measurement

Collect the amount of drainage in the bag and record it.

Secondary outcomes

1

Description

Transfusion during and after surgery.

Timepoint

During surgery up to 24 hours after surgery.

Method of measurement

The number of blood bags injected into the patient.

Intervention groups

1

Description

Intervention group: Injection of one gram of tranexamic acid to the patient before surgery.

Category

Treatment - Drugs

Recruitment centers

1

Recruitment center

Name of recruitment center

Shahid Modarres hospital

Full name of responsible person

Dr. Ramin Baghayi Tehrani

Street address

Cardiovascular Research Center, Saadat Abad Shahid
Modares Hospital, Tehran

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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. Ramin Baghayi Tehrani

Street address

Cardiovascular Research Center, Saadat Abad Shahid
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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

1

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

Dr. Ramin Baghayi Tehrani

Position

faculty member (associate professor)

Latest degree

Subspecialist

Other areas of specialty/work

General Surgery

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Cardiovascular Research Center, Saadat Abad Shahid
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Person responsible for updating data

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

Information on primary and secondary outcomes and patient demographics will be shared on the condition that patients remain anonymous.

When the data will become available and for how long

After printing the results of the study, it will be possible to access the data if the readers request from the responsible author.

To whom data/document is available

Anyone interested in research in this field.

Under which criteria data/document could be used

After the results of the study are published, the data will be made available to the researchers upon request from the corresponding author.

From where data/document is obtainable

corresponding author. Dr. Ramin Baghai Tehrani. Located in Shahid Modares Hospital. Department of cardiac surgery. To zip code 1998734383.

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

Depending on the busyness of the corresponding author, the data will be delivered within a week.

Comments