

Clinical Trial Protocol

Iranian Registry of Clinical Trials

16 Jul 2026

The effect of local fibrinogen administration on postoperative bleeding in CABG patients

Protocol summary

Summary

This randomized clinical trial assessed the effect of local fibrinogen on the amount of postoperative bleeding and the need for blood transfusion in adult patients undergoing CABG to compare the results with local placebo

General information

Acronym

IRCT registration information

IRCT registration number: **IRCT201510222804N9**

Registration date: **2015-12-08, 1394/09/17**

Registration timing: **registered_while_recruiting**

Last update:

Update count: **0**

Registration date

2015-12-08, 1394/09/17

Registrant information

Name

Ali Dabbagh

Name of organization / entity

Country

Iran (Islamic Republic of)

Phone

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Email address

alidabbagh@sbmu.ac.ir

Recruitment status

Recruitment complete

Funding source

Shahid Beheshti University of Medical Sciences

Expected recruitment start date

2015-09-30, 1394/07/08

Expected recruitment end date

2016-02-29, 1394/12/10

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

The effect of local fibrinogen administration on postoperative bleeding in CABG patients

Public title

The effect of local fibrinogen administration on postoperative bleeding in CABG patients

Purpose

Prevention

Inclusion/Exclusion criteria

Inclusion criteria: age between 40-75 years old; elective CABG with CPB; constant surgeon; informed written consent. The following conditions were considered as exclusion criteria: emergent or urgent surgery; age more than 75 years or less than 40 years old; diabetes mellitus (or any of its complications like diabetic ketoacidosis or non-ketonic hyperosmolar diabetic coma); any previous history of stroke or underlying cerebral vascular disease; history of deep vein thrombosis; history of underlying hematologic disorders; any carotid plaque creating significant stenosis (stenosis > 75%); underlying pulmonary disorders affecting the spirometry indices significantly (>50% decrease); acute renal failure; chronic kidney disease causing serum Cr>2mg/dL; hepatic failure causing liver function test failure (> 3 times than normal); off pump CABG; any unwanted complication in the operation period; re-starting CPB after weaning from bypass; pulmonary artery pressure >30 before operation; ejection fraction<30%; congestive heart failure.

Age

From **40 years** old to **75 years** old

Gender

Both

Phase
3

Groups that have been masked
No information

Sample size
Target sample size: 50

Randomization (investigator's opinion)
Randomized

Randomization description

Blinding (investigator's opinion)
Double blinded

Blinding description

Placebo
Used

Assignment
Parallel

Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee
Shahid Beheshti University of Medical Sciences

Street address
Velenjak; Chamran Exp Way; Tehran; Iran

City
Tehran

Postal code
1417613151

Approval date
2011-06-02, 1390/03/12

Ethics committee reference number
1567

Health conditions studied

1

Description of health condition studied
coronary artery bypass graft

ICD-10 code
I25.1

ICD-10 code description
Atherosclerotic heart disease

Primary outcomes

1

Description
Postoperative bleeding

Timepoint
Early 24 hours in postoperative period

Method of measurement

Postoperative amount of blood loss in chest tube bottles

Secondary outcomes

1

Description
Hematocrit level

Timepoint
Early 24 hours hematocrit in postoperative period

Method of measurement
Preoperative and postoperative hematocrit level

Intervention groups

1

Description
After weaning from cardiopulmonary bypass and infusion of protamine, "fibrinogen" solution including 1 g of fibrinogen in 50 mL volume is flushed over the heart Afterwards, sternum is closed and wired with steel wires. The surgeon is blind to the content of the 50 mL syringes; whether fibrinogen or placebo.

Category
Treatment - Drugs

2

Description
In the control (placebo) group, after weaning from bypass circuit and protamine infusion, 50 mL of distilled water is flushed over the heart, exactly the same method as fibrinogen. Finally afterwards, sternum is closed and wired with steel wires. The surgeon is blind to the content of the 50 mL syringes; whether fibrinogen or placebo.

Category
Placebo

Recruitment centers

1

Recruitment center

Name of recruitment center
Shahid Modarres Hospital

Full name of responsible person
Ali Dabbagh

Street address
Modarres Hospital, Saadat Abad

City
Tehran

Sponsors / Funding sources

1

Sponsor

Name of organization / entity
Vice chancellor for research, Shahid Beheshti

University of Medical Sciences
Full name of responsible person
 Dr Afshin Zarghi
Street address
 Shahid Beheshti University of Medical Sciences,
 Velenjak, Chamran Exp Way
City
 Tehran
Grant name
Grant code / Reference number
Is the source of funding the same sponsor organization/entity?
 Yes
Title of funding source
 Vice chancellor for research, Shahid Beheshti University
 of Medical Sciences
Proportion provided by this source
 100
Public or private sector
 empty
Domestic or foreign origin
 empty
Category of foreign source of funding
 empty
Country of origin
Type of organization providing the funding
 empty

Person responsible for general inquiries

Contact
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Sharing plan

Deidentified Individual Participant Data Set (IPD)
 empty
Study Protocol
 empty
Statistical Analysis Plan
 empty
Informed Consent Form
 empty
Clinical Study Report
 empty
Analytic Code
 empty
Data Dictionary
 empty