Clinical Trial Protocol
Iranian Registry of Clinical Trials

30 May 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

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Shahid Beheshti University of Medical Sciences, Velenjak, Chamran Exp Way

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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
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

Name of organization / entity
Anesthesiology Research Center

Full name of responsible person
Ali Dabbagh

Position
MD, Professor

Other areas of specialty/work

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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