Clinical Trial Protocol
Iranian Registry of Clinical Trials

08 Jul 2026

Effect of Prophylactic Fibrinogen Concentrate Infusion on Postoperative Bleeding in Coronary Artery Bypass Graft Surgery: a Randomized, Double-Blinded Clinical Trial

Protocol summary

Summary

In this prospective, randomized, double-blind study, a total number of 60 patients undergoing coronary artery bypass surgery were randomly divided into two groups. The fibrinogen group were administered 1 g of fibrinogen concentrate preoperatively in contrast to the placebo group. Bleeding volumes and PT, PTT, INR and hemoglobin and blood products administered to both groups, were recorded postoperatively.

General information

Acronym

IRCT registration information

IRCT registration number: **IRCT201011085140N1**
Registration date: **2011-06-07, 1390/03/17**
Registration timing: **retrospective**

Last update:
Update count: **0**

Registration date

2011-06-07, 1390/03/17

Registrant information

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Recruitment status

Recruitment complete

Funding source

Private

Expected recruitment start date

2009-01-25, 1387/11/06

Expected recruitment end date

2010-06-29, 1389/04/08

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Effect of Prophylactic Fibrinogen Concentrate Infusion on Postoperative Bleeding in Coronary Artery Bypass Graft Surgery: a Randomized, Double-Blinded Clinical Trial

Public title

Effect of prophylactic fibrinogen on post operative bleeding in coronary artery bypass graft surgery

Purpose

Prevention

Inclusion/Exclusion criteria

Inclusion criteria: All candidates for first time elective coronary artery bypass graft surgery. Exclusion criteria: 1-Previously diagnosed hematologic or liver disease, 2-uncontrolled or insulin dependent diabetic mellitus, 3-pregnancy, 4-unstable angina, 5-serum creatinine > 130 µmol/L, 6-left ventricular ejection fraction of less than 35% prior to surgery, 7-serum fibrinogen levels of more than 3/5 g/L.

Age

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

Gender

Both

Phase

N/A

Groups that have been masked
No information
Sample size
Target sample size: **60**
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
Ethic comittee, Faculty of medicine of Tehran university of Medical Sciences
Street address
Second floor, Faculty of Medicine, Tehran University of Medical Sciences and Health Care
City
Tehran
Postal code
Approval date
2009-01-10, 1387/10/21
Ethics committee reference number
379/1002

Health conditions studied

1

Description of health condition studied
Hemorrhage
ICD-10 code
D68.3
ICD-10 code description
Hemorrhage, not elsewhere classified

Primary outcomes

1

Description
volume of postoperative hemorrhage
Timepoint
0,12,24h after surgery
Method of measurement
overall chest tube drainage during the first 24 hour postoperative hours and was recorded by a pre-trained intensive care unit nurse

Secondary outcomes

1

Description
transfusion of blood products
Timepoint
first 24 hours post surgery
Method of measurement
The amount of transfused red pack cells, fresh frozen plasma, and platelets during the first 24 hour post-surgery

Intervention groups

1

Description
control group: the patients were administered 1 gr of placebo dissolved in 50 millimeters of normal saline over a 15 minute period after induction of anesthesia before the start of surgery.
Category
Placebo

2

Description
Interventional group: In the fibrinogen group the patients were administered 1 gr of fibrinogen dissolved in 50 millimeters of normal saline over a 15 minute period after induction of anesthesia before the start of surgery
Category
Treatment - Drugs

Recruitment centers

1

Recruitment center
Name of recruitment center
Dr.Ali Shariati Hospital
Full name of responsible person
Street address
City
Tehran

Sponsors / Funding sources

1

Sponsor
Name of organization / entity
Tehran University of Medical Sciences
Full name of responsible person
Shahin Akhoondzadeh
Street address
Vice Chancellor for research , Tehran University of Medical Sciences
City
Tehran

Grant name
Grant code / Reference number
Is the source of funding the same sponsor organization/entity?
Yes
Title of funding source
Tehran 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

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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