

# 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

###### Name

Omid Azimaraghi

###### Name of organization / entity

Tehran University of Medical Sciences

###### Country

Iran (Islamic Republic of)

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+98 21 2206 6194

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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 committee, 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

### Contact

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## Person responsible for scientific inquiries

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## Person responsible for updating data

### 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*