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

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
None

Sample size
Target sample size: 60

Randomization (investigator's opinion)
Randomized

Blinding (investigator's opinion)
Double blinded

Recruitment status
Recruitment complete

Funding source
Private

Expected recruitment start date
2009-01-25, 1387/11/06
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
Person responsible for general inquiries

Contact
Name of organization / entity
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Fax
Email
Web page address

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