Clinical Trial Protocol
Iranian Registry of Clinical Trials

16 Sep 2026

Comparison of the effect of prophylactic fibrinogen and placebo infusion on perioperative bleeding in posterior spinal fusion surgery, a randomized clinical trial

Protocol summary

Summary

The main aim of the study is evaluating the effect of prophylactic fibrinogen injection on intraoperative bleeding in PSF surgeries comparing to control group. Study population: All patients candidate for PSF surgery between 18 to 60 years old and needed sample size is 42. Method: After inclusion in the study, one gram fibrinogen would be infused preoperatively. Amount of bleeding during the operation, level of serum fibrinogen before and after surgery and the number of blood bags infused during the surgery would be measured and compared to the control group. inclusion criteria: ASA I,II patients candidate for elective posterior spine fusion surgery, age 18-60y, BMI less than 30 kg/m2, duration of surgery between 1-4 h, Exclusion criteria: history of previous PSF, pulmonary, cardiac, hepatic, renal or coagulation disorders, hypertension; beta blocker, calcium blocker, digoxine, TCAs, Anticoagulant and clonidin consumption by patient, alcohol or drug abuse, existing tumor in the site of surgery, surgery in more than 3 levels. The main intervention is fibrinogen infusion before spine surgery. The patients will be divided to fibrinogen and placebo groups,using a computerized random number table. The outcomes are measuring rate of bleeding during operation, hemoglobin and serum fibrinogen level changes before and after surgery and the number of transfused blood to patients and comparing to control group. Patients and the person responsible for measuring the amount of bleeding will be unaware about type of intervention.

General information

Acronym

IRCT registration information

IRCT registration number: **IRCT201307304969N8**

Registration date: **2015-04-22, 1394/02/02**

Registration timing: **retrospective**

Last update:

Update count: **0**

Registration date

2015-04-22, 1394/02/02

Registrant information

Name

Alireza Pournajafian

Name of organization / entity

Tehran University of Medical Sciense

Country

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Recruitment status

Recruitment complete

Funding source

Iran University of Medical Sciences, Vice chancellor for research

Expected recruitment start date

2012-09-22, 1391/07/01

Expected recruitment end date

2014-09-23, 1393/07/01

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Comparison of the effect of prophylactic fibrinogen and placebo infusion on perioperative bleeding in posterior

spinal fusion surgery, a randomized clinical trial

Public title
Effect of Fibrinogen infusion on bleeding amount during spine surgery
Purpose
Prevention
Inclusion/Exclusion criteria
Inclusion criteria: Patients candidate for elective posterior spine fusion surgery, preoperative serum fibrinogen level between 2-4 g/l, ASA I,II , age 18-60y, BMI less than 30 kg/m2, duration of surgery between 1-4 h, Exclusion criteria: history of previous PSF, pulmonary, cardiac, hepatic, renal or coagulation disorders, hypertension, using beta blocker, calcium blocker, digoxine, TCAs, anticoagulant and clonidin by patient, alcohol or drug abuse, existing tumor in the site of surgery, surgery in more than 3 levels
Age
From **18 years** old to **60 years** old
Gender
Both

Phase
2-3
Groups that have been masked
No information
Sample size
Target sample size: **42**
Randomization (investigator's opinion)
Randomized
Randomization description
Blinding (investigator's opinion)
Single blinded
Blinding description
Placebo
Not used
Assignment
Parallel
Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee
Name of ethics committee
Ethics committee of Iran University of Medical Sciences
Street address
Next to Milad Tower- Hemmat Highway
City
Tehran
Postal code
Approval date
2014-12-03, 1393/09/12
Ethics committee reference number
93/d/105/4272

Health conditions studied

1

Description of health condition studied
Intraoperative massive bleeding
ICD-10 code
D69.9
ICD-10 code description
Hemorrhagic condition, unspecified

Primary outcomes

1

Description
Amount of bleeding
Timepoint
during surgery and in recovery room
Method of measurement
Watching scaled bottle of suction in milliliter

2

Description
Number of infused Blood bags
Timepoint
At the end of surgery
Method of measurement
Counting the number of infused blood bags

3

Description
serum fibrinogen
Timepoint
just before and the day after surgery
Method of measurement
Special laboratory kit for measuring fibrinogen

4

Description
Hemoglobin
Timepoint
The day before and 4 hours after surgery
Method of measurement
Measurement of hemoglobin by laboratory

Secondary outcomes

empty

Intervention groups

1

Description
Infusion of 1 g fibrinogen powder(CSL Behring,USA) in 20 milliliter saline normal intravenously before anesthesia in case group
Category

Prevention

2

Description
Infusion of 20 milliliter saline normal before anesthesia in control group
Category
Placebo

Recruitment centers

1

Recruitment center
Name of recruitment center
Firoozgar Hospital
Full name of responsible person
Alireza Pournajafian
Street address
Beh Afarin St.- Karim khan Blvd.
City
Tehran

Sponsors / Funding sources

1

Sponsor
Name of organization / entity
Iran University of Medical Sciences, Vice chancellor for research
Full name of responsible person
Dr. Ali Javad Mousavi
Street address
Next to Milad Tower- Hemmat Highway
City
Tehran
Grant name
Grant code / Reference number
Is the source of funding the same sponsor organization/entity?
Yes
Title of funding source
Iran University of Medical Sciences, Vice chancellor for research
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
Firoozgar Hospital
Full name of responsible person
Alireza Pournajafian
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Person responsible for updating data

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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