

Clinical Trial Protocol

Iranian Registry of Clinical Trials

09 Jun 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 Science

Country

Iran (Islamic Republic of)

Phone

+98 21 8894 6762

Email address

drpournajafian@iums.ac.ir

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

Position

Assistant Professor of Anesthesia

Other areas of specialty/work

Street address

Beh Afarin st.- Karim khan Ave.

City

Tehran

Postal code

Phone

+98 21 8894 6762

Fax

Email

alipn78@yahoo.com

Web page address

Person responsible for scientific inquiries

Contact

Name of organization / entity

Iran University of Medical Sciences

Full name of responsible person

Alireza Pournajafian

Position

Assistant Professor of Anesthesia

Other areas of specialty/work

Street address

Beh Afarin St.- Karim khan Ave.

City

Tehran

Postal code

Phone

+98 21 8894 6762

Fax

Email

alipn78@yahoo.com

Web page address

Person responsible for updating data

Contact

Name of organization / entity

Firoozgar Hospital

Full name of responsible person

Alireza Pournajafian

Position

Assistant Professor of Anesthesia

Other areas of specialty/work

Street address

Beh Afarin St.- Karim khan Ave.

City

Tehran

Postal code

Phone

+98 21 8894 6762

Fax

Email

alipn78@yahoo.com

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