Clinical Trial Protocol
Iranian Registry of Clinical Trials

23 Jul 2026

Comparison of effectiveness of Different doses of prophylactic intravenous fibrinogen versus normal saline on intraoperative bleeding in posterior spinal fusion surgery

Protocol summary

Study aim
Determining the appropriate dose of prophylactic fibrinogen effective in reducing the amount of intraoperative bleeding

Design
A clinical trial , control group, parallel groups, double-blind, randomized, phase 3 on 120 patients, randomized permutation block was used for randomization.

Settings and conduct
Each patient will have a sealed envelope containing data group information and will be opened in the operating room by a designated nurse. The anesthesiologist prepares and prescribes the drugs for everyone. Patients undergo induction of similar anesthesia after pre-oxygenation. The amount of bleeding during the operation is calculated from the weight of the gases and the amount of blood in the suction. 15-30 minutes before surgery, all three groups receive two 50 cc infusion syringes (the first group fibrinogen and normal saline, the second group two fibrinogen syringes and the control group two normal saline syringes). At the end of the operation, the total amount of bleeding, the need for transfusion, the number of pack injection units, and the length of the surgery are evaluated.

Participants/Inclusion and exclusion criteria
No history of drug allergies, thromboembolism and coagulation disorders, use of anticoagulants, history of blood disorders and coagulopathy,

Intervention groups
After induction of anesthesia in group F1, 1gr and in group F2, 2gr of fibrinogen and in the control group the same normal volume of saline will be injected intravenously. All patients are monitored by standard and depth of anesthesia. And will have intermittent IPC. All will be operated on by a PSF surgeon. The total amount of bleeding, the need for transfusion, the number of pack cell injection units and the length of surgery are assessed.

Main outcome variables
Intraoperative bleeding rate, comparison of different doses of prophylactic fibrinogen

General information

Reason for update

Acronym

IRCT registration information
IRCT registration number: **IRCT20210415050983N3**
Registration date: **2023-02-17, 1401/11/28**
Registration timing: **prospective**

Last update: **2023-02-17, 1401/11/28**
Update count: **0**

Registration date
2023-02-17, 1401/11/28

Registrant information

Name
Sogol Asgari

Name of organization / entity

Country
Iran (Islamic Republic of)

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+98 21 8836 3185

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Recruitment status
Recruitment complete

Funding source

Expected recruitment start date
2023-05-05, 1402/02/15

Expected recruitment end date
2023-08-06, 1402/05/15

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Comparison of effectiveness of Different doses of prophylactic intravenous fibrinogen versus normal saline on intraoperative bleeding in posterior spinal fusion surgery

Public title

Comparison of effectiveness of Different doses of prophylactic intravenous fibrinogen versus normal saline on intraoperative bleeding in posterior spinal fusion surgery

Purpose

Health service research

Inclusion/Exclusion criteria

Inclusion criteria:

No history of drug allergy No history of thromboembolism and coagulation disorders No history of liver or kidney failure No history of heart disease and hypertension ASA I , II Patient consent to participate in the study

Exclusion criteria:

use of anticoagulants History of blood disorders and coagulopathy History of liver disease History of chronic kidney disease and creatinine greater than 2mg / dl History of thromboembolic events at any time

Age

From **18 years** old to **50 years** old

Gender

Both

Phase

3

Groups that have been masked

- Participant
- Care provider
- Outcome assessor
- Data analyser

Sample size

Target sample size: **40**

Randomization (investigator's opinion)

Randomized

Randomization description

Permuted Randomized Blocks :In this method, 10 random blocks are generated by computer. Each block includes 5 people in the intervention group and 5 people in the control group. The order of these people is randomly arranged by computer and people are assigned to groups in the same way. At the end of each block, a new block of 10 is produced and this process will continue until the final sample volume is reached.

Blinding (investigator's opinion)

Double blinded

Blinding description

Forms with numbers 1 and 2 are used in packaged envelopes to group patients, which are given to patients randomly and patients do not know about the envelopes. After entering the envelope operating room by the anesthesiologist in charge of the patient Opened and according to the intervention group, the drug that was prepared in advance is given to the clinical caregiver for injection. The clinical caregiver is not aware of the grouping. The evaluator and recorder of the results and the person analyzing the data are also unaware of the grouping.

Placebo

Not used

Assignment

Parallel

Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee

Vice for Research and Technology, Shahid Beheshti University of Medical Sciences

Street address

Velenjak, Yemen Street, Shahid Shahriari Square

City

Tehran

Province

Tehran

Postal code

1985717443

Approval date

2022-10-18, 1401/07/26

Ethics committee reference number

IR.SBMU.MSP.REC.1401.365

Health conditions studied

1

Description of health condition studied

Lumbar Discopathy

ICD-10 code

M51.05

ICD-10 code description

Intervertebral disc disorders with myelopathy, thoracolumbar region

Primary outcomes

1

Description

Determination of intraoperative bleeding in groups receiving fibrinogen and control group

Timepoint

End of surgery

Method of measurement

Bleeding volume during field operation, blood gases, suction

2

Description
Determining the duration of surgery in the groups receiving fibrinogen and the control group
Timepoint
End of surgery
Method of measurement
hours / minutes

3

Description
Amount of blood and blood products injected
Timepoint
End of surgery
Method of measurement
The number of units to be injected

4

Description
Comparison of different doses of prophylactic fibrinogen on the above outcomes
Timepoint
End of surgery
Method of measurement
Fibrinogen one gram and two grams

Secondary outcomes

1

Description
Determining the duration of surgery in the groups receiving fibrinogen and the control group
Timepoint
End of surgery
Method of measurement
hours / minutes

2

Description
Determination of recovery time after reverse dose injection in groups receiving fibrinogen and control group
Timepoint
End of surgery
Method of measurement
hours / minutes

3

Description
Determining the length of stay in the intensive care unit in the groups receiving fibrinogen and the control group
Timepoint
End of surgery
Method of measurement
hours / minutes

Intervention groups

1

Description
Intervention group: They are divided into two groups receiving one gram of fibrinogen (F1) and two grams of fibrinogen (F2). Ten minutes after the operation, the first group received 1 gram of fibrinogen concentrate (Haemocomplettan P; CSL Behring, Pennsylvania) intravenously. which is dissolved in 50 ml of distilled water, as described by the manufacturer, the second group receives 2 grams of fibrinogen
Category
Treatment - Drugs

2

Description
Control group: They receive an equal volume of placebo (normal saline) 10 minutes after the start of the operation.
Category
Treatment - Drugs

Recruitment centers

1

Recruitment center
Name of recruitment center
Loghman Hakim Hospital
Full name of responsible person
Sogol Asgari
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South Kargar St. - Kamali St. - Special St
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Sponsors / Funding sources

1

Sponsor
Name of organization / entity
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Full name of responsible person
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Grant name

Grant code / Reference number

Is the source of funding the same sponsor organization/entity?
Yes

Title of funding source
Shahid Beheshti University of Medical Sciences

Proportion provided by this source
100

Public or private sector
Public

Domestic or foreign origin
Domestic

Category of foreign source of funding
empty

Country of origin

Type of organization providing the funding
Academic

Person responsible for general inquiries

Contact

Name of organization / entity
Shahid Beheshti University of Medical Sciences
Full name of responsible person
Sogol Asgari
Position
Assistant Professor
Latest degree
Subspecialist
Other areas of specialty/work
Anesthesiology
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Person responsible for updating data

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Sharing plan

Deidentified Individual Participant Data Set (IPD)
Undecided - It is not yet known if there will be a plan to make this available

Study Protocol
Undecided - It is not yet known if there will be a plan to make this available

Statistical Analysis Plan
Undecided - It is not yet known if there will be a plan to make this available

Informed Consent Form
Undecided - It is not yet known if there will be a plan to make this available

Clinical Study Report
Undecided - It is not yet known if there will be a plan to make this available

Analytic Code
Undecided - It is not yet known if there will be a plan to

make this available	
Data Dictionary	Undecided - It is not yet known if there will be a plan to make this available