Clinical Trial Protocol
Iranian Registry of Clinical Trials

01 Jun 2026

Comparison of intravenous tranexamic acid and intravenous fibrinogen on bleeding control in posterior lumbar spine fusion surgery.

Protocol summary

Study aim
Comparison of tranexamic acid and fibrinogen in posterior fusion bleeding of the lumbar spine

Design
A clinical trial , control group, parallel groups, double-blind, randomized, phase 3 on 120 patients(Each group 40 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 surgical incision, all three groups receive two 50 cc infusion syringes (the first group tranexamic acid and normal saline, the second group fibrinogen and normal saline 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
Inclusion:No history of drug allergies, thromboembolism and coagulation disorders Exclusion: use of anticoagulants, history of blood disorders and coagulopathy

Intervention groups
After induction of anesthesia in group 1, 15mg/kg tranexamic acid and in group 2, 1gr of fibrinogen and in the control group the same volume of normal 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 tranexamic acid and fibrinogen

General information

Reason for update
Acronym
IRCT registration information
IRCT registration number: **IRCT20210415050983N4**
Registration date: **2023-03-06, 1401/12/15**
Registration timing: **prospective**

Last update: **2023-03-06, 1401/12/15**
Update count: **0**

Registration date
2023-03-06, 1401/12/15

Registrant information
Name
Sogol Asgari
Name of organization / entity
Country
Iran (Islamic Republic of)
Phone
+98 21 8836 3185
Email address
drasgari98429@sbmu.ac.ir

Recruitment status
Recruitment complete
Funding source

Expected recruitment start date
2023-04-21, 1402/02/01
Expected recruitment end date
2023-08-23, 1402/06/01
Actual recruitment start date
empty
Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Comparison of intravenous tranexamic acid and intravenous fibrinogen on bleeding control in posterior lumbar spine fusion surgery.

Public title

Comparison of intravenous tranexamic acid and intravenous fibrinogen on bleeding control in posterior lumbar spine 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 Software R. 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.1401.353

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 tranexamic acid ,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 tranexamic acid ,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

Secondary outcomes

1

Description

Determining the duration of surgery in the groups receiving tranexamic acid ,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 tranexamic acid ,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 tranexamic acid ,fibrinogen and the control group

Timepoint

End of surgery

Method of measurement

hours / minutes

Intervention groups

1

Description

The group receiving tranexamic acid: 15-30 minutes before surgical incision, 15mg/kg tranexamic acid, which has been diluted with normal saline to a volume of 20 cc, will be administered intravenously.

Category

Treatment - Drugs

2

Description

Fibrinogen receiving group: 15-30 minutes before surgical incision, one gram of Fibrinogen concentrate (Haemocomplettan P; CSL Behring, Pennsylvania) dissolved in 50 ml of distilled water was administered intravenously as described by the manufacturer they receive .

Category

Treatment - Drugs

3

Description

Control group: They receive an equal volume of placebo (normal saline) 30 minutes before surgical incision.

Category

Treatment - Drugs

Recruitment centers

1

Recruitment center

Name of recruitment center

Loghman Hakim Hospital

Full name of responsible person

Sogol Asgari

Street address

South Kargar St. - Kamali St. - Special St

City

Tehran

Province

Tehran

Postal code

1333635445

Phone

+98 21 5102 5291

Email

Drasgari98429@gmail.com

Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Shahid Beheshti University of Medical Sciences

Full name of responsible person

Dr. Seyed Ali Ziaei

Street address

Velenjak, Yemen Street, Shahid Shahriari Square

City

Tehran

Province

Tehran

Postal code

1985717443

Phone

+98 21 23871

Email

aliziai@sbmu.ac.ir

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

Street address

South Kargar St. Kamali St. Special Loghman Hakim Hospital

City

Tehran

Province

Tehran

Postal code

1333635445

Phone

+98 21 5541 9005

Email

Drasgari98429@gmail.com

Person responsible for scientific inquiries

Contact

Name of organization / entity

Shahid Beheshti University of Medical Sciences

Full name of responsible person

Parisa Sezari

Position

Assistant Professor

Latest degree

Specialist

Other areas of specialty/work

Anesthesiology

Street address

Velenjak, Yemen Street, Shahid Shahriari Squareولنجک خیابان یمن میدان شهید شهریاری شهر Tehran

City

Tehran

Province

Tehran

Postal code

1985717443

Phone

+98 21 23871

Email

parisa.sezari@gmail.com

Person responsible for updating data

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

Street address

Velenjak, Yemen Street, Shahid Shahriari Square

City

Tehran

Province

Tehran

Postal code

1985717443

Phone

+98 21 23871

Email

Drasgari98429@gmail.com

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