Clinical Trial Protocol
Iranian Registry of Clinical Trials

16 Sep 2026

Evaluation of the Effect of Intravenous Tranexamic Acid in Reducing the Amount of Intraoperative Bleeding in Major Lumbar Spinal Surgeries with Instruments (A Randomized Double-blind Clinical Trial Study)

Protocol summary

Study aim

1. Reducing the need for blood transfusion 2. Stable hemodynamic status 3. Reducing the duration of anesthesia 4. Reducing the duration of the operation 5. Reducing the duration of hospitalization 6. Reducing the risk of infection

Design

A clinical trial with a control group and an intervention group, double-blind, randomized, phase 3 on 84 patients. A table of random numbers is used for randomization.

Settings and conduct

The study is carried out in Shahid Madani Hospital of Alborz province. In the intervention group, 30 minutes before the skin incision, 10 _ 15 mg/kg of intravenous Tranexamic acid as a loading dose and during the operation 1 _ 2 mg/kg/hr as maintenance dose is injected until the end of the procedure. in the control group, placebo (Normal Saline 0.9%) is injected 30 minutes before the operation as a loading dose and during the operation as a maintenance dose with a equal volume to Tranexamic acid injected in the intervention group. The surgeon and the patient are blinded. Tranexamic acid and placebo are injected to the patients with syringe No. 1 (for intervention) and syringe No. 2 (for control) respectively, by the anesthesiologistbased on the mentioned dose.

Participants/Inclusion and exclusion criteria

Entry conditions: Degenerative spine patients needing instrumentation Conditions of non-entry: lack of patient consent, use of anticoagulant drugs, congenital coagulopathy disease, history of any type of cerebral hemorrhage, history of anaphylactic reaction, pregnant women, history of DVT and PTE.

Intervention groups

The intervention group (42 patients) is injected with Tranexamic acid and the control group (42 patients) is injected with placebo.

Main outcome variables

1. Bleeding volume during operation 2. The volume of blood collected daily in the Hemovac drain after the operation

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20230519058227N1**
Registration date: **2023-07-04, 1402/04/13**
Registration timing: **prospective**

Last update: **2023-07-04, 1402/04/13**
Update count: **0**

Registration date

2023-07-04, 1402/04/13

Registrant information

Name

Nima Bagheri

Name of organization / entity

Country

Iran (Islamic Republic of)

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Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2023-08-11, 1402/05/20

Expected recruitment end date

2023-10-12, 1402/07/20

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Evaluation of the Effect of Intravenous Tranexamic Acid in Reducing the Amount of Intraoperative Bleeding in Major Lumbar Spinal Surgeries with Instruments (A Randomized Double-blind Clinical Trial Study)

Public title

Effect of Intravenous Tranexamic Acid in Reducing in Spinal Surgeries

Purpose

Treatment

Inclusion/Exclusion criteria

Inclusion criteria:

A patient with far lateral lumbar disc herniation who requires instrumentation. A patient with lumbar spinal stenosis who requires instrumentation. A patient with Spondylolisthesis who requires instrumentation. A patient with Scoliosis who requires instrumentation. A patient with Lordosis who requires instrumentation. A patient has a extensive fracture of the lumbar vertebrae who requires instrumentation.

Exclusion criteria:

Patient dissatisfaction Patients taking Anticoagulant Drugs. People with Congenital Coagulopathy. Patients who have a history of any type of Cerebral Hemorrhage such as SAH, ICH, SDH, EDH, IVH. Patients who have a history of Anaphylactic Reaction. Women who are pregnant. Patients who have a history of DVT and PTE. Patients who have a history of Chronic Renal Failure (Cr-baseline > 1.36 mg/dl). Patients with Chronic Liver Disease. Patients who have Platelets < 100,000 mm3. Patients who have INR > 1.5. Patients who have PT > 14. Patients who have PTT > 35.

Age

No age limit

Gender

Both

Phase

3

Groups that have been masked

- Participant
- Care provider

Sample size

Target sample size: **84**

Randomization (investigator's opinion)

Randomized

Randomization description

In this study, based on the limited randomization method, the degenerative spine patients in need of instrumentation were divided into an intervention group (group A) and control group (group B) by the method of random blocks with variable sizes obtained by the table of random numbers (with zero, even and odd numbers). There are equal numbers of intervention groups and control groups in each block. Sequentially numbered, sealed opaque envelopes are also used for allocation concealment. In this way, a number of letter envelopes are prepared with an aluminum wrapper (in order to obscure the content of the envelopes) and each of the random sequences created is recorded on a card and the cards are placed in the letter envelopes in order. In order to maintain the random sequence, the outer surface of the envelopes is numbered in the same order. Finally, the lid of the letter envelopes is glued and placed in a box. At the time of registration of participants, based on the order of entry of qualified participants into the study, one of the envelopes will be opened and the assigned group of that participant will be revealed.

Blinding (investigator's opinion)

Double blinded

Blinding description

It is a double-blind study (surgeon _ patient). For this purpose, an ampoule of Tranexamic acid called syringe No. 1 (for injection in group A) and a placebo called syringe No. 2 (for injection in group B) are prepared. The anesthesiologist give injections to the patients 30 minutes before the operation and during the operation (based on the dose mentioned in the methods) according to the specified random block method. The surgeon knows which patients have participated in the study, The surgeon knows which patients have participated in the study, but no one except the anesthesiologist knows the type of injectable ampoule. Also, all patients know that they have participated in this study, but they do not know about the type of injectable ampoule.

Placebo

Used

Assignment

Other

Other design features

In this study, based on the sample size calculations, 84 patients are selected and with the random allocation method, the patients will be divided into the intervention group (group A) and the control group (group B) based on the random block design. The intervention group will be injected intravenous Tranexamic acid, and the control group will receive a placebo.

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee

Research Ethics Committees of Alborz University of Medical Sciences

Street address

45 Meters Golshahr Ave, Saffarian Alley, Deputy of Research and Technology

City

Karaj

Province

Alborz

Postal code
3198764653
Approval date
2023-06-10, 1402/03/20
Ethics committee reference number
IR.ABZUMS.REC.1402.078

Health conditions studied

1

Description of health condition studied
Far lateral lumbar disc herniation
ICD-10 code
ICD-10 code description

2

Description of health condition studied
Lumbar spinal stenosis
ICD-10 code
ICD-10 code description

3

Description of health condition studied
Spondylolisthesis
ICD-10 code
ICD-10 code description

4

Description of health condition studied
Scoliosis
ICD-10 code
ICD-10 code description

5

Description of health condition studied
Lordosis
ICD-10 code
ICD-10 code description

6

Description of health condition studied
Extensive fracture of the lumbar vertebrae
ICD-10 code
ICD-10 code description

Primary outcomes

1

Description
Bleeding volume during operation
Timepoint
During operation
Method of measurement
By collecting the amount of blood in the suction and subtracting its amount from the amount of serum that was used in the washing place (the amount of serum used is noted) and counting the number of blood cells approximately.

2

Description
The volume of blood collected daily in the hemovac drain after the operation
Timepoint
After installing the Hamovac drain on a daily basis
Method of measurement
The amount of blood collected in the Hemovac drain is charted daily in coordination with the surgeon.

Secondary outcomes

empty

Intervention groups

1

Description
Intervention group: In the intervention group (group A), 30 minutes immediately before the skin incision,10 _ 15 mg/kg of intravenous Tranexamic acid as a loading dose (do not exceed the injection of 100 mg/min) and during the operation 1 _ 2 mg/kg/hr as maintenance dose is injected until the end of the procedure.
Category
Treatment - Drugs

2

Description
In the control group (group B), placebo (normal saline 0.9%) is injected 30 minutes before the operation as a loading dose and during the operation as a maintenance dose with a equal volume to Tranexamic acid injected in the intervention group.
Category
Placebo

Recruitment centers

1

Recruitment center
Name of recruitment center
Shahid Madani hospital
Full name of responsible person
Mohammad Kamangar
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Shahid Madani hospital, Shahid Madani Square, Mahan Blv, Taleghani crossroads
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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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research@abzums.ac.ir
Grant name
Grant code / Reference number
Is the source of funding the same sponsor organization/entity?
Yes
Title of funding source
Karaj 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
Karaj University of Medical Sciences
Full name of responsible person
Nima Bagheri
Position
Medical Internship
Latest degree
A Level or less
Other areas of specialty/work
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Sharing plan

Deidentified Individual Participant Data Set (IPD)

Yes - There is a plan to make this available

Study Protocol

Yes - There is a plan to make this available

Statistical Analysis Plan

Yes - There is a plan to make this available

Informed Consent Form

Yes - There is a plan to make this available

Clinical Study Report

Yes - There is a plan to make this available

Analytic Code

Not applicable

Data Dictionary

Not applicable

Title and more details about the data/document

All data is potentially shareable after de-identifying individuals.

When the data will become available and for how long

6 months after the final data analysis

To whom data/document is available

Departments and researchers of neurosurgery around the world

Under which criteria data/document could be used

1. No unauthorized use of the delivered data 2. Obtaining a written undertaking not to misuse data

From where data/document is obtainable

1. Dr. Mohammad Kamangar (Neurosurgeon) Email: dr_mkamangar@yahoo.com 2. Dr. Nima Bagheri (Medical Internship) Email: nima1376nba@yahoo.com

What processes are involved for a request to access data/document

Sending Email and presenting documents to be a member of the Neurosurgery Department

Comments