

# Clinical Trial Protocol

## Iranian Registry of Clinical Trials

06 Jul 2026

### Assessment the efficacy of Tranexamic Acid in reducing blood loss after laminectomy and postrolateral fusion of spine

#### Protocol summary

##### Study aim

Investigating the Effect of Transaxin Intravenous Acid on Reducing Post-Laminectomy Bleeding and Spinal Fibrinolysis

##### Design

This study was a randomized, randomized clinical trial on 60 patients with lumbar laminectomy and fissure

##### Settings and conduct

This study will be carried out at Tabriz Imam Reza Hospital in the form of a triple -blind, only the head nurse will be aware of it, and the patient and the patient will be unaware of it.

##### Participants/Inclusion and exclusion criteria

Criteria for inclusion in the study include patients aged 20-60 years who are candidates for laminectomy of 2 or more spaces, and fistula with a pedicelular screw (CD insertion) for any cause other than trauma, as well as having informed consent and reading skills. And writing. Exclusion criteria include the use of anticoagulant drugs such as ASA and depiridamole, high PT, PTT, INR for any cause, history of any thrombotic events, such as CVA and MI, history of bleeding disorders, history of TBI and history of CPR, kidney failure , Taking OCP, pregnancy or breastfeeding. Also, patients who have undergone blood transfusion before surgery for any reason will also be excluded from the study

##### Intervention groups

Patients between the ages of 20 and 60 who are candidates for laminectomy 2 or more space and fissure with a pedicle screw (CD insertion) for any cause other than trauma at the end of the surgery and before the final fixation and drainage of the trance Topical hexamic acid will be used

##### Main outcome variables

Transfusionized blood levels in patients undergoing surgery

#### General information

##### Reason for update

##### Acronym

##### IRCT registration information

IRCT registration number: **IRCT20120527009878N6**

Registration date: **2019-04-04, 1398/01/15**

Registration timing: **registered\_while\_recruiting**

Last update: **2019-04-04, 1398/01/15**

Update count: **0**

##### Registration date

2019-04-04, 1398/01/15

##### Registrant information

##### Name

Firooz Salehpour

##### Name of organization / entity

##### Country

Iran (Islamic Republic of)

##### Phone

+98 41 3334 0830

##### Email address

salehpourf@tbzmed.ac.ir

##### Recruitment status

**Recruitment complete**

##### Funding source

##### Expected recruitment start date

2019-03-18, 1397/12/27

##### Expected recruitment end date

2022-03-18, 1400/12/27

##### Actual recruitment start date

empty

##### Actual recruitment end date

empty

##### Trial completion date

empty

##### Scientific title

Assessment the efficacy of Tranexamic Acid in reducing blood loss after laminectomy and postrolateral fusion of spine

#### Public title

Assessment the efficacy of Tranexamic Acid in reducing blood loss after laminectomy and postrolateral fusion of spine

#### Purpose

Treatment

#### Inclusion/Exclusion criteria

##### Inclusion criteria:

Patients with candidate laminectomy and fissure-medial fistula, who refer to Imam Reza Hospital in Tabriz all patients aged 20 to 60 years

##### Exclusion criteria:

Use of anticoagulant drugs such as ASA and depiridamole high PT, PTT, INR for any cause history of any thrombotic event such as CVA and MI history of bleeding disorders history of TBI history of CPR kidney failure OCP use, pregnancy Or lactation. Also, patients who need blood transfusion before or during surgery for any reason

#### Age

From **20 years** old to **60 years** old

#### Gender

Both

#### Phase

N/A

#### Groups that have been masked

- Participant
- Care provider
- Data analyser

#### Sample size

Target sample size: **50**

#### Randomization (investigator's opinion)

Randomized

#### Randomization description

The selected patients will be divided into two groups of TXA receptors (n = 25) and placebo recipients (n = 25) according to the random numbers table. All surgical procedures in this study were performed by a surgical team and the technique used was similar. The randomization in this study is that TXA (15 mg / kg) in single dose and placebo (normal saline 0.09%), which are pre-prepared with the names 1 and 2 in separate syringes, are exactly Prior to cutting by anesthetist technician, an uncontrolled intravenous anesthesia is administered to the patient and the patient is injected randomly, and then an operation is performed on the patient.

#### Blinding (investigator's opinion)

Triple blinded

#### Blinding description

The selected patients who enter the operating room will be divided into two groups of TXA receptors (n = 25) and placebo recipients (n = 25) according to the random numbers table, which will be informed by the nurse of the operating room. And they will not be aware of it during the operation of the surgical team. All surgical procedures in this study were performed by a surgical

team and the technique used was similar. The statistical analyzer is also unaware of the drug method. The basis of the study will be three blinds. After analysis, the head nurse will be asked the type 1 and 2 methods.

#### Placebo

Used

#### Assignment

Parallel

#### Other design features

## Secondary Ids

empty

## Ethics committees

### 1

#### Ethics committee

##### Name of ethics committee

Ethics Committee of Tabriz Medical science

##### Street address

Azadi Ave , Golghast St , Imam Reza Hospital

##### City

Tabriz

##### Province

East Azarbaijan

##### Postal code

5166614756

#### Approval date

2019-03-12, 1397/12/21

#### Ethics committee reference number

ir.tbzmed.rec.1397.1012

## Health conditions studied

### 1

#### Description of health condition studied

Topical administration of TXA helps control bleeding and prevents unwanted side effects

#### ICD-10 code

M48.06

#### ICD-10 code description

Spinal stenosis, lumbar region

## Primary outcomes

### 1

#### Description

Determination of the Effect of Tranexamic Acid on the Transfusion Level of Blood Transfusion in Patients under Laminectomy and Fibrous Fistula

#### Timepoint

During surgery and duration of hospitalization after surgery

#### Method of measurement

Blood volume injected to the patient in milliliters

## 2

### **Description**

Determination of the Effect of Tranexamic Acid on the Length of Hospitalization During Laminectomy and Fistula

### **Timepoint**

During surgery and duration of hospitalization after surgery

### **Method of measurement**

Duration of hospitalization in hospital days

## 3

### **Description**

Determine the effect of tranexamic acid on the amount of blood collected in hemovac in patients undergoing laminectomy and fissure of the posterolateral of the spine.

### **Timepoint**

duration of hospitalization after surgery

### **Method of measurement**

The amount of blood accumulated in CC

## **Secondary outcomes**

empty

## **Intervention groups**

### 1

#### **Description**

Intervention group: Patients between the ages of 20 and 60 who are candidates for laminectomy 2 or more space and fissure with a pedicle screw (CD insertion) for any cause other than trauma at the end of the surgery and before the final fixation and drainage of the trance Topical hexamic acid will be used.

#### **Category**

Treatment - Drugs

### 2

#### **Description**

Control group: Patients aged between 20 and 60 years who are candidates for laminectomy of 2 or more spaces and fistula with a pedicle screw (CD insertion) for any cause other than trauma at the end of the surgery and before the final fixation and embedding Dren will use the drug.

#### **Category**

Placebo

## **Recruitment centers**

### 1

#### **Recruitment center**

##### **Name of recruitment center**

Imam Reza Hospital

##### **Full name of responsible person**

Mansour Valaie

#### **Street address**

Azadi St., Golghast St.,

#### **City**

Tabriz

#### **Province**

East Azarbaijan

#### **Postal code**

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#### **Phone**

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#### **Fax**

#### **Email**

Shakerym@tbzmed.ac.ir

#### **Web page address**

<https://imamreza.tbzmed.ac.ir>

## **Sponsors / Funding sources**

### 1

#### **Sponsor**

##### **Name of organization / entity**

Deputy of Research of Tabriz University

##### **Full name of responsible person**

Ali Meshkini

##### **Street address**

Azadi St., Golghast St.,

##### **City**

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##### **Phone**

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##### **Email**

Meshkini@gmail.com

#### **Grant name**

#### **Grant code / Reference number**

#### **Is the source of funding the same sponsor organization/entity?**

Yes

#### **Title of funding source**

Deputy of Research of Tabriz University

#### **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**

Tabriz University of Medical Sciences

##### **Full name of responsible person**

Moslem Shakeri

**Position**

Associate professor

**Latest degree**

Specialist

**Other areas of specialty/work**

Neurosurgery

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**Person responsible for scientific inquiries**

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resident

**Latest degree**

Medical doctor

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Neurosurgery

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**Position**

resident

**Latest degree**

Medical doctor

**Other areas of specialty/work**

Neurosurgery

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**Phone**

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**Email**

mvalaie@tbzmed.ac.ir

**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