Clinical Trial Protocol
Iranian Registry of Clinical Trials

16 Sep 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
5166614756
Phone
+98 44 1333 8507
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
Tabriz
Province
East Azarbaijan
Postal code
5166614756
Phone
+98 44 1446 9326
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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Golgasht ave
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Province
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Email
shakeri@tbzmed.ac.ir

Person responsible for scientific inquiries

Contact
Name of organization / entity
Tabriz University of Medical Sciences
Full name of responsible person
Mansour Valaie
Position
resident
Latest degree
Medical doctor
Other areas of specialty/work
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City
Tabriz
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Phone
+98 44 1333 8507
Email
mvalaie@tbzmed.ac.ir
Web page address

Person responsible for updating data

Contact
Name of organization / entity
Tabriz University of Medical Sciences
Full name of responsible person
Mansour valaie
Position
resident
Latest degree
Medical doctor
Other areas of specialty/work
Neurosurgery
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Golgasht ave
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Tabriz
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5166614756
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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