Clinical Trial Protocol
Iranian Registry of Clinical Trials

05 Aug 2026

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

Protocol summary

Summary

There are new studies about positive effects of TXA; Reduce in bleeding after posterolateral fusion surgeries and some level laminectomies could be interesting clinically; so this study designed. Inclusion Criteria: age between 18 to 60 years old; patients underwent for laminectomy surgery (2 level or more) and posterolateral fusion with pedicule screws for reason other than trauma , Informed consent Exclusion Criteria: Anticoagulant drugs use such as A.S.A and dipyridamole; Increased in PT, PTT, INR; History of CVA, MI, bleeding disorder, TBI, CPR, Renal Failure, OCP; Pregnancy and breastfeeding 5- Patients received pack cell before or during the operation. Patients will be divided in 2 groups based on tables of random numbers. Case group will receive TXA 15 mg/kg for single dose (N=25) and control group will receive placebo (N=25). All surgical technique is the same for both group. After moving to section the amount of bleeding in hemobag in period of first 12 hours and the second 12 hours will measured. Blood loss during the operation and need to transfusion, the duration of hospitalization and side effects will compared

General information

Acronym

IRCT registration information

IRCT registration number: **IRCT2017020913947N6**
Registration date: **2017-04-14, 1396/01/25**
Registration timing: **retrospective**

Last update:
Update count: **0**

Registration date

2017-04-14, 1396/01/25

Registrant information

Name

Atta Mahdkhah

Name of organization / entity

Tabriz University of Medical Sciences

Country

Iran (Islamic Republic of)

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Recruitment status

Recruitment complete

Funding source

Investigator

Expected recruitment start date

2014-03-21, 1393/01/01

Expected recruitment end date

2016-03-20, 1395/01/01

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:age between 18 to 60 years old ; patients underwent for laminectomy surgery (2 level or more) and posterolateral fusion with pedicule screws for reason other than trauma ; Informed consent Exclusion

Criteria: Anticoagulant drugs use such as A.S.A and dipyridamole; Increased in PT, PTT, INR ; History of CVA, MI, bleeding disorder, TBI, CPR, Renal Failure, OCP; Pregnancy and breastfeeding; Patients received pack cell before or during the operation

Age
From **18 years** old to **60 years** old

Gender
Both

Phase
2

Groups that have been masked
No information

Sample size
Target sample size: **50**

Randomization (investigator's opinion)
Randomized

Randomization description

Blinding (investigator's opinion)
Double blinded

Blinding description

Placebo
Used

Assignment
Parallel

Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee
Ethics Committee and Research,Tabriz University of Medical Sciences

Street address
Tabriz

City
Tabriz

Postal code

Approval date
2017-03-06, 1395/12/16

Ethics committee reference number
IR.TBZMED. REC.1395.1292

Health conditions studied

1

Description of health condition studied
Anticoagulant drug

ICD-10 code
Y44.3

ICD-10 code description
Anticoagulant antagonists, vitamin K and other coagulants

Primary outcomes

1

Description
blood loss

Timepoint
First and 12 hours after surgery and

Method of measurement
First and 12 hours after surgery and the amount of suctioned during surgery

Secondary outcomes

empty

Intervention groups

1

Description
Intervention group will receive TXA 15 mg/kg for single dose

Category
Treatment - Drugs

2

Description
Control group: will receive placebo

Category
Placebo

Recruitment centers

1

Recruitment center

Name of recruitment center
Imam Reza Hospital, Tabriz University of Medical Sciences

Full name of responsible person
Moslem Shakeri

Street address
Tabriz, Iran

City
Tabriz

Sponsors / Funding sources

1

Sponsor

Name of organization / entity
Vice chancellor for research, Tabriz University of Medical Sciences, Golgasht St, Tabriz, Iran

Full name of responsible person
Moslem Shakeri

Street address
Tabriz, East Azarbaijan, Iran

City
Tabriz

Grant name
Grant code / Reference number
Is the source of funding the same sponsor organization/entity?
Yes
Title of funding source
Vice chancellor for research, Tabriz University of Medical Sciences, Golgasht St, Tabriz, Iran
Proportion provided by this source
100
Public or private sector
empty
Domestic or foreign origin
empty
Category of foreign source of funding
empty
Country of origin
Type of organization providing the funding
empty

Person responsible for general inquiries

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Sharing plan

Deidentified Individual Participant Data Set (IPD)
empty
Study Protocol
empty
Statistical Analysis Plan
empty
Informed Consent Form
empty
Clinical Study Report
empty
Analytic Code
empty
Data Dictionary
empty