Clinical Trial Protocol
Iranian Registry of Clinical Trials

16 Sep 2026

The effect of oral Tranexamic Acid for bleeding in Spinal Surgery

Protocol summary

Study aim

This study aimed to evaluate the effect of oral Tranexamic acid (TXA) on the amount of bleeding during spine surgery.

Design

A Randomized Double-Blind, Placebo-controlled Clinical Trial

Settings and conduct

patients with lumbar spinal cord and back pain disease, who needed fusion or were candidates for bilateral or more or equal to two levels surgeries, referred to the Department of Neurosurgery, were included. All patients eligible for inclusion in the study were randomly divided into two equal groups (double-blind). The intervention group included 64 patients who received 25 mg/kg of TXA four times a day before the surgery and 500 mg in the morning of surgery. Placebo group included 65 patients who received the placebo. It should be noted that the subjects (patients) and researcher (Neurosurgery resident) are not aware of the type of medication.

Participants/Inclusion and exclusion criteria

Participants: patients with lumbar spinal cord and back pain disease; inclusion criteria: being in a range of ages 18-60, lack of cardiovascular disease, discopathies with spinal fusion, and discopathies more than two levels or two-sided spinal cord; exclusion criteria: dissatisfaction to participate in the study, abnormal bleeding, platelet count < 150,000 (k), a history of thrombosis or embolism, severe allergies, use of intermittent medications with hemostasis in the blood, high blood pressure uncontrolled (PB> 160/90), obese people (BMI> 30)

Intervention groups

The intervention group will receive 25 mg/kg of Tranexamic Acid orally four times a day before the surgery and 500 mg in the morning of surgery. The placebo group will also receive a total dose of 2-g small pills that are identical in appearance but contained no active ingredient.

Main outcome variables

The amount of bleeding in patients during the operation will be calculated based on the count of blood gases and suction content.

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20190525043701N1**
Registration date: **2019-08-02, 1398/05/11**
Registration timing: **prospective**

Last update: **2019-08-02, 1398/05/11**
Update count: **0**

Registration date

2019-08-02, 1398/05/11

Registrant information

Name

Normohammad Mamizadeh

Name of organization / entity

Country

Iran (Islamic Republic of)

Phone

+98 61 3321 9452

Email address

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Recruitment status

Not yet recruiting

Funding source

Expected recruitment start date

2640-10-02, 2019/07/10

Expected recruitment end date

2641-03-11, 2019/12/20

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date
empty

Scientific title
The effect of oral Tranexamic Acid for bleeding in Spinal Surgery

Public title
Oral Tranexamic Acid in Spinal Surgery
Purpose
Treatment
Inclusion/Exclusion criteria
Inclusion criteria:
being in a range of ages 18 to 60 lack of cardiovascular disease Patients undergoing lumbar and back spine surgery, including discopathies with spinal fusion, and discopathies more than two levels or two-sided spinal cord.
Exclusion criteria:
unwillingness to participate in the study abnormal bleeding platelet count less than 150,000 (k) a history of thrombosis or embolism severe allergies using drugs that interact with hemostasis in the blood high and uncontrolled blood pressure (blood pressure mre than 160/90) obese people (body mass index more than 30).
Age
From **18 years** old to **60 years** old
Gender
Both

Phase
N/A
Groups that have been masked

- Participant
- Care provider
- Investigator
- Outcome assessor
- Data analyser

Sample size
Target sample size: **129**
Randomization (investigator's opinion)
Randomized
Randomization description
Patients will be randomized on the basis of random numbers table in two groups of recipients TXA (n = 64) and placebo recipients (n = 65). All surgical procedures in this study were performed by a surgical team and the technique used was similar. The randomization in this study will be done as TXA group (25 mg/kg) received four tablets of 500 mg and the placebo group also received a full dose of 2 mg of small pills that appeared to be the same but dose not contain any active substance.
Blinding (investigator's opinion)
Double blinded
Blinding description
the subjects (patients) and researcher (Neurosurgery resident) are not aware of the type of medication. After collecting the data and the results of their analysis by the implementer, the type of each drug is identified and all surgeries are performed to control the confounding factors by a surgeon, and there is only one anesthesiologist for all patients.
Placebo
Used
Assignment
Parallel
Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee
Name of ethics committee
Ahvaz Jundishapur University of Medical Sciences' Ethics Committee
Street address
Golestan Blvd., Farvardin Street
City
Ahvaz
Province
Khouzestan
Postal code
33118-61357
Approval date
2018-02-14, 1396/11/25
Ethics committee reference number
IR.AJUMS.REC.1396.1125

Health conditions studied

1

Description of health condition studied
The effect of oral Tranexamic Acid for bleeding in Spinal Surgery
ICD-10 code
D69.9
ICD-10 code description
Hemorrhagic condition, unspecified

Primary outcomes

1

Description
The amount of Bleeding after Oral Administration of Tranexamic acid
Timepoint
Before and after intervention will measure.
Method of measurement
The amount of blood collected in cc

Secondary outcomes

1

Description
The coagulation tests

Timepoint
Will be checked during and 72 hours after the operation.
Method of measurement
According to standard one-stage APTT method

Intervention groups

1

Description
Intervention group: Patients aged 18 to 60 years who are candidates for spinal surgery for any cause other than trauma, will be used on the day before surgery and 500 mg on the morning of surgery of the Trancehexamic acid (TXA) .
Category
Treatment - Drugs

2

Description
Control group: Patients between the ages of 18 and 60 who are candidates for spinal surgery for any reason other than trauma will be used placebo pills on the day before surgery and 500 mg in the morning of surgery.
Category
Placebo

Recruitment centers

1

Recruitment center
Name of recruitment center
Golestan hospital
Full name of responsible person
Nour Mohammad Mamizadeh
Street address
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Sponsors / Funding sources

1

Sponsor
Name of organization / entity
Ahvaz University of Medical Sciences
Full name of responsible person
Mohammad badavi
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Grant name
Grant code / Reference number
Is the source of funding the same sponsor organization/entity?
Yes
Title of funding source
Ahvaz 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
Ahvaz University of Medical Sciences
Full name of responsible person
Nour Mohammad Mamizadeh
Position
resident
Latest degree
Medical doctor
Other areas of specialty/work
Neurosurgery
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Sharing plan

Deidentified Individual Participant Data Set (IPD)
No - There is not a plan to make this available
Justification/reason for indecision/not sharing IPD
There is no further information
Study Protocol
Yes - There is a plan to make this available
Statistical Analysis Plan
No - There is not a plan to make this available
Informed Consent Form
No - There is not a plan to make this available
Clinical Study Report
Yes - There is a plan to make this available
Analytic Code
Yes - There is a plan to make this available
Data Dictionary
Not applicable
Title and more details about the data/document
All collected data will be available.
When the data will become available and for how long
starting in January 2020
To whom data/document is available
Not only people working in academic institutions also people working in businesses can also apply to receive data.
Under which criteria data/document could be used
There are no other conditions.
From where data/document is obtainable
Applicants can apply for this by e-mail.
What processes are involved for a request to access data/document
Allow receipt by email.
Comments