

Clinical Trial Protocol

Iranian Registry of Clinical Trials

13 Jun 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

mamizadeh.n@ajums.ac.ir

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

Golestan blv

City

Ahvaz

Province

Khuzestan

Postal code

6153715794

Phone

+98 61 3336 7562

Fax

+98 61 3336 7562

Email

mhmdmamizadeh@gmail.com

Sponsors / Funding sources**1****Sponsor****Name of organization / entity**

Ahvaz University of Medical Sciences

Full name of responsible person

Mohammad badavi

Street address

Golestan blv

City

Ahvaz

Province

Khuzestan

Postal code

6153715794

Phone

+98 61 3336 7562

Fax

+98 61 3336 7562

Email

Research@ajums.ac.ir

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

Street address

Golestan Blvd., Farvardin Street

City

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Province

Khuzestan

Postal code

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Phone

+98 61 3374 3032

Fax

+98 61 3374 3032

Email

mhmdmamizadeh@gmail.com

Person responsible for scientific inquiries

Contact

Name of organization / entity

Ahvaz University of Medical Sciences

Full name of responsible person

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Position

resident

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Fax

+98 61 3374 3032

Email

mhmdmamizadeh@gmail.com

Person responsible for updating data

Contact

Name of organization / entity

Ahvaz University of Medical Sciences

Full name of responsible person

Nour Mohammad Mamizadeh

Position

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Fax

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Email

mhmdmamizadeh@gmail.com

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