

Clinical Trial Protocol

Iranian Registry of Clinical Trials

02 Jun 2026

Evaluation of Therapeutic Effect of Tranexamic Acid Infusion on Reducing Blood loss during Neurosurgery in Traumatic Brain Injury Patients with Subdural and Epidural Hemorrhage Referred to Golestan Hospital in Ahwaz

Protocol summary

Summary

Aim of this study is determining the therapeutic effects of intravenous administration of TXA in reducing the amount of intraoperative bleeding head during injury in patients with subdural and epidural hemorrhage bleeding. Participants should be over 18 years, and 8 hours after the accident to the emergency room is reached. Also do not have external bleeding skull, such as intra-abdominal hemorrhage. If a woman was pregnant and Hematuria occurred and anticoagulant drugs and aspirin have been used, they excluded from study. The study population were patients that were admitted to Golestan hospital in Ahvaz and ntracranial hemorrhage and subdural and epidural necessity to perform neurosurgery on clinical status is certified by neurosurgeons review. Sample size was 40 patients. The intervention group will receive a package containing four vials of 500 mg TXA or placebo and two sterile syringe size 21. The drug is administered as a loading dose (1g TXA added added to 100 ml of 0.9% normal saline and intravenous infusion over 10 minutes) and the maintenance dose (1 g TXT added to 500 ml of 0.9% normal saline and intravenous infusion over 8 hours) were administered by nurses. Control group will receive normal saline 0.9% instead of drug in same conditions. Injector and staff nurses in emergency medicine do not know anything about drug and placebo pocket. The primary outcome is determining amount of bleeding during surgery.

General information

Acronym

IRCT registration information

IRCT registration number: **IRCT2016031027003N1**

Registration date: **2016-08-04, 1395/05/14**

Registration timing: **registered_while_recruiting**

Last update:

Update count: **0**

Registration date

2016-08-04, 1395/05/14

Registrant information

Name

Pouya Ebrhimi

Name of organization / entity

Ahvaz Jondishapour University of Medical Sciences

Country

Iran (Islamic Republic of)

Phone

+98 21 2274 2052

Email address

ebrahimi.p@ajums.ac.ir

Recruitment status

Recruitment complete

Funding source

Ahvaz Jondishapour University of Medical Sciences

Expected recruitment start date

2016-05-21, 1395/03/01

Expected recruitment end date

2017-10-22, 1396/07/30

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Evaluation of Therapeutic Effect of Tranexamic Acid Infusion on Reducing Blood loss during Neurosurgery in

Traumatic Brain Injury Patients with Subdural and Epidural Hemorrhage Referred to Golestan Hospital in Ahwaz

Public title

Evaluation of therapeutic effect of Tranexamic Acidinfusion during neurosurgery

Purpose

Treatment

Inclusion/Exclusion criteria

Inclusion criteria : age is over 18 years old; -in- eight hours after the accident to the emergency room Golestan is reached; trauma to the head and bleeding intracranial subdural and epidural on a CT scan of the brain; absence of significant cranial bleeding such as intra-abdominal hemorrhage; absence of fracture or deformity of limbs; absence of subarachnoid hemorrhage; absence of hematuria; not known coagulopathy; necessity to perform neurosurgery on clinical status and terms of neurosurgeons. Exclusion criteria : The proof of the existence of pregnancy; The presence of intracranial hemorrhage or subdural and epidural hematoma , along with the addition; The need to FFP transfusion or injection solid; hematuria; The presence of subarachnoid hemorrhage; anticoagulant drugs and aspirin.

Age

From **18 years** old

Gender

Both

Phase

N/A

Groups that have been masked

No information

Sample size

Target sample size: **40**

Randomization (investigator's opinion)

Randomized

Randomization description

Blinding (investigator's opinion)

Double blinded

Blinding description

Placebo

Used

Assignment

Parallel

Other design features

randomization was done by random number table

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee

Ahwaz Jondishapour University of Medical Sciences

Street address

Ahwaz, Golestan Blvd

City

Ahwaz

Postal code

Approval date

2016-01-21, 1394/11/01

Ethics committee reference number

IR.AJUMS.REC.1394.680

Health conditions studied

1

Description of health condition studied

Intracranial injury

ICD-10 code

S06.4 - S0

ICD-10 code description

Epidural haemorrhage Traumatic subdural haemorrhage

Primary outcomes

1

Description

Amount of bleeding during surgery

Timepoint

during surgery

Method of measurement

Suctioned blood volume measurement

Secondary outcomes

1

Description

Duration of time of hospitalization

Timepoint

After surgery

Method of measurement

Day

2

Description

Result of functional Test

Timepoint

after surgery

Method of measurement

Examinations conducted by researcher

3

Description

Duration of surgery

Timepoint

At time of surgery

Method of measurement

Document of patients

Intervention groups

1

Description

The intervention group will receive a package containing four vials of 500 mg TXA or placebo and two sterile syringe size 21. The drug is administered as a loading dose (1 g TXA added to 100 ml of 0.9% normal saline and intravenous infusion over 10 minutes) and the maintenance dose (1 g TXA added to 500 ml of 0.9% normal saline and intravenous infusion over 8 hours) will be administered by nurses.

Category

Treatment - Drugs

2

Description

The control group will receive a package containing four vials of 500 mg placebo and two sterile syringe size 21. The drug is administered as a loading dose (1 g Normal saline 0.9% added to 100 ml of 0.9% normal saline and intravenous infusion over 10 minutes) and the maintenance dose (1 g Normal saline 0.9% added to 500 ml of 0.9% normal saline and intravenous infusion over 8 hours) will be administered by nurses.

Category

Treatment - Drugs

Recruitment centers

1

Recruitment center

Name of recruitment center

Ahvaz Golestan Hospital

Full name of responsible person

Javad Mozafari

Street address

Golestan blvd - Golestan hospital - Ahvaz

City

Ahvaz

Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Ahvaz Jondishapour University of Medical Sciences

Full name of responsible person

Javad Mozafari

Street address

Golestan Blvd, Golestan hospital

City

Ahvaz

Grant name

Grant code / Reference number

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

Yes

Title of funding source

Ahvaz Jondishapour University of Medical Sciences

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

Contact

Name of organization / entity

Ahvaz Jundishapour University of Medical Sciences

Full name of responsible person

Javad Mozafari

Position

Doctor of Philosophy

Other areas of specialty/work

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Person responsible for scientific inquiries

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Full name of responsible person

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Pouya Ebrahimi

Position

Student of Doctor of Philosophy

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Web page address**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