

Clinical Trial Protocol

Iranian Registry of Clinical Trials

29 May 2026

Evaluation of therapeutic effect of Tranexamic Acid infusion on reducing blood loss during neurosurgery in Traumatic Brain injury patients with intraparenchymal hemorrhage

Protocol summary

Summary

Aim of this triple blind clinical trial is determining the therapeutic effects of intravenous administration of TXA in reducing the amount of intraoperative bleeding during surgery in head trauma patients with Intraparenchymal hemorrhage. Participants should be over 18 years, and should attend to the emergency room during first 8 hours after the accident. Also they shouldn't have extracranial bleeding, such as intra-abdominal hemorrhage. Pregnancy, hematuria and usage of anticoagulants and aspirin are other exclusion criteria. The study population are patients who are admitted to Golestan hospital in Ahvaz and their diagnosis of intracranial hemorrhage requiring neurosurgery is confirmed by neurosurgeons. Total Sample size is 40 patients. The intervention group will receive a package containing four vials of 500 mg TXA 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 condition. Injector and staff nurses, radiologist and statistician are blind in this study. The primary outcome is determining amount of bleeding during surgery.

General information

Acronym

IRCT registration information

IRCT registration number: **IRCT2016031427051N1**
Registration date: **2016-09-04, 1395/06/14**
Registration timing: **registered_while_recruiting**

Last update:

Update count: **0**

Registration date

2016-09-04, 1395/06/14

Registrant information

Name

Maryam Mousavinejad

Name of organization / entity

Ahvaz Jondishapour University of Medical Sciences

Country

Iran (Islamic Republic of)

Phone

+98 66 3340 6155

Email address

mousavinejad.sm@ajums.ac.ir

Recruitment status

Recruitment complete

Funding source

Vice Chancellor for research of Ahvaz 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 intraparenchymal hemorrhage

Public title

Evaluation of Therapeutic Effect of Tranexamic Acid Infusion on Intraparenchymal Hemorrhage

Purpose

Treatment

Inclusion/Exclusion criteria

Inclusion criteria : age over 18 years old; attendance to the emergency room within the first 8 hours of the accident; trauma to the head with Intraparenchymal hemorrhage (IPH) on brain CT scan; absence of significant extra-cranial hemorrhage such as intra-abdominal hemorrhage; absence of fracture or deformity of limbs; absence of subarachnoid hemorrhage; absence of hematuria; absence of known coagulopathy; necessity to perform neurosurgery in clinical evaluation and according to neurosurgeon's opinion. Exclusion criteria :Existence of pregnancy; the presence of other types of intracranial hemorrhage other than intraparenchymal hematoma; need to FFP or massive whole blood transfusion; hematuria; presence of subarachnoid hemorrhage; usage of anticoagulant drugs and aspirin.

Age

No age limit

Gender

Both

Phase

2-3

Groups that have been masked

No information

Sample size

Target sample size: 40

Randomization (investigator's opinion)

Randomized

Randomization description

Blinding (investigator's opinion)

Triple 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

Ethics committee of Ahvaz Jondishapour University of Medical Sciences

Street address

Ahvaz, Golestan Blvd

City

Ahvaz

Postal code

Approval date

2016-01-21, 1394/11/01

Ethics committee reference number

IR.AJUMS.REC.1394.679

Health conditions studied

1

Description of health condition studied

Intracranial injury

ICD-10 code

S06.3

ICD-10 code description

Focal brain injury

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 hospitalization

Timepoint

After surgery

Method of measurement

according to patient's documents

2

Description

Result of functional Test

Timepoint

28 days after surgery or at time of discharge

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 and two sterile syringe size

21.The drug is administered as a loading dose (1g TXA 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) 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 (1g Normalsaline added to 100 ml of 0.9% normal saline and intravenous infusion over 10 minutes) and the maintenance dose (1 g Normal saline added to 500 ml of 0.9% normal saline and intravenous infusion over 8 hours) will be administered by

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 hospital, Golestan Blvd, Ahvaz

City

Ahvaz

Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Vice challenge for research of Ahvaz Jondishapour University of Medical Sciences

Full name of responsible person

Javad Mozafari

Street address

Golestan hospital, Golestan Blvd

City

Ahvaz

Grant name

Grant code / Reference number

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

Yes

Title of funding source

Vice challenge for research of 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

Ph.D

Other areas of specialty/work

Street address

Golestan hospital, Golestan Blvd

City

Ahvaz

Postal code

Phone

+98 61 3374 3079

Fax

Email

Mozafari.taha@yahoo.com

Web page address

Person responsible for scientific inquiries

Contact

Name of organization / entity

Ahvaz Jundishapour University of Medical Sciences

Full name of responsible person

Javad Mozafari

Position

Ph.D

Other areas of specialty/work

Street address

Golestan hospital, Golestan Blvd

City

Ahvaz

Postal code

Phone

+98 61 3374 3079

Fax

Email

Mozafari.taha@yahoo.com

Web page address

Person responsible for updating data

Contact

Name of organization / entity

Ahvaz Jundishapour University of Medical Sciences

Full name of responsible person

Seyede Maryam Mousavinejad

Position

Medical student

Other areas of specialty/work

Street address

Golestan hospital, Golestan Blvd

City

Ahvaz

Postal code

Phone

+98 21 2274 2052

Fax

Email

mousavinejad.sm@ajums.ac.ir

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