

Clinical Trial Protocol

Iranian Registry of Clinical Trials

10 Jun 2026

Comparing intravenous infusion of Tranexamic Acid to prevent the progression of cerebral hemorrhage in patients with traumatic brain injury with placebo

Protocol summary

Summary

Due to high incidence of head trauma and its complications (epidural hematoma, subdural hematoma, intracerebral hemorrhage, and intraventricular hemorrhage), this study aims to examine the effect of Tranexamic acid compared to the placebo in reducing development of brain hemorrhage. The other purposes of this study include reducing the number of days of hospitalization at Intensive Care Unit (ICU), and reduction of mortality rate of traumatic brain hemorrhage. All over-18-year-old patients with the above mentioned bleeding in recent 8 hours are considered in this study after obtaining consent from the patient or his legal guardian. This single-center study is conducted at emergency department of Shahid Rahnamoun Hospital. This study is done on 50 patients, including two 25-member groups that receive drug and placebo in a double-blind and randomized manner. Tranexamic acid is prescribed at a dose of 1g/500ml of normal saline by intravenous infusion. Hemorrhage volume is compared in CT scan of admission time and after 24 hours. The main outcome variables are blood volume, the number of days of ICU care, and the mortality rate (in case of death in the first seven days). To make the study blind, at the beginning of the shift, the drug and placebo are coded and injected in the same number, shape and volume syringe, using the table of random numbers. Patients and researcher are unaware of the content of the injection. because of anti-fibrinolytic and partial anti-inflammatory effects of Tranexamic acid, it is expected that this drug can reduce the cerebral hemorrhage progression.

General information

Acronym

IRCT registration information

IRCT registration number: **IRCT2015090423890N1**

Registration date: **2015-11-21, 1394/08/30**
Registration timing: **registered_while_recruiting**

Last update:
Update count: **0**

Registration date
2015-11-21, 1394/08/30

Registrant information

Name
Fatemeh Modjallal Najjar
Name of organization / entity
Shahid Sadoughi University of Medical Sciences
Country
Iran (Islamic Republic of)
Phone
+98 35 3823 5055
Email address
fmodjallal@ssu.ac.ir

Recruitment status

Recruitment complete

Funding source

Vice chancellor for research, Shahid Sadoughi University of Medical Sciences of Yazd

Expected recruitment start date

2015-09-23, 1394/07/01

Expected recruitment end date

2016-03-19, 1394/12/29

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Comparing intravenous infusion of Tranexamic Acid to

prevent the progression of cerebral hemorrhage in patients with traumatic brain injury with placebo

Public title

the effect of tranexamic acid on cerebral hemorrhage

Purpose

Prevention

Inclusion/Exclusion criteria

Inclusion Criteria:1) The age above 18 years old 2) The existence of hemorrhage in brain CT scan including subdural hematoma, epidural hematoma ,intra cerebral hemorrhage and intraventricular hemorrhage 3) less than 8 hours passed from trauma 4) The absence of coagulopathy Exclusion criteria: 1) Performing craniotomy

Age

From **18 years** old

Gender

Both

Phase

N/A

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 of Yazd Shahid Sadoughi University of Medical Sciences

Street address

Shahid Sadoughi University of Medical Sciences, Shahid Bahonar Square

City

Yazd

Postal code

8916978477

Approval date

2014-10-07, 1393/07/15

Ethics committee reference number

IR.SSU.MEDICINE.REC.1393.31

Health conditions studied**1****Description of health condition studied**

Head injury

ICD-10 code

S06.3 - S0

ICD-10 code description

traumatic intracerebral haemorrhage , Epidural haemorrhage Extradural haemorrhage (traumatic), Traumatic subdural haemorrhage

Primary outcomes**1****Description**

brain hemorrhage volume

Timepoint

Before intervention and 24 hours after intervention

Method of measurement

Volume in ml of blood in the brain CT scan on the hospital's network. It calculate by multiplying the maximum length in maximum width in number of cuts of hemorrhage in centimeter divided by the 2,and registering on designed form

Secondary outcomes**1****Description**

The number of days of hospitalization in the intensive care unit

Timepoint

From admission of the patient until transmitting him/her from the ICU to the ward.

Method of measurement

Counting the number of days from entry and exit register in intensive care unite

2**Description**

Died in the first seven days of hospitalization

Timepoint

Seven days after hospitalization

Method of measurement

Using the registry of death in hospital

Intervention groups**1****Description**

Intervention 1: Tranexamic acid 500 mg per 5 ml ampule of Caspian Tamin pharmaceutical company intravenous infusion at a single dose of 1 gr in 8 hours from trauma

Category

Treatment - Drugs

2

Description

Intervention 2: Intravenous infusion of 10 cc Normal Saline

Category

Treatment - Drugs

Recruitment centers

1

Recruitment center

Name of recruitment center

Shahid Dr. Rahnamoon Hospital

Full name of responsible person

Fatemeh Modjallal Najjar

Street address

Shahid Dr. Rahnamoon Hospital, Farrokhi St.

City

Yazd

Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Vice chancellor for research, Shahid Sadoughi University of Medical Sciences

Full name of responsible person

Amir Houshang Mehrparvar

Street address

Vice chancellor for research, Shahid Sadoughi University of Medical Science, Shahid Bahonar square

City

Yazd

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, Shahid Sadoughi 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

Vice chancellor for research, Shahid Sadoughi

University of Medical Sciences

Full name of responsible person

Fatemeh Modjallal Najjar

Position

Medical Doctor/Emergency Medicine Resident

Other areas of specialty/work

Street address

Shahid Sadoughi University of Medical Sciences, Shahid Bahonar Sq.

City

Yazd

Postal code

۸۹۱۶۹۷۸۴۷۷

Phone

+98 358235055

Fax

Email

fmojallal@ssu.ac.ir,fmodjallal@yahoo.com

Web page address

Person responsible for scientific inquiries

Contact

Name of organization / entity

Shahid Sadoughi University of Medical Sciences

Full name of responsible person

Mehdi Bagherabadi

Position

Emergency Medicine Specialist

Other areas of specialty/work

Street address

Shahid Sadoughi University of Medical Science, Shahid Bahonar Sq.

City

Yazd

Postal code

89195-741

Phone

+98 358261158

Fax

Email

Mehdi.bagherabadi@yahoo.com

Web page address

Person responsible for updating data

Contact

Name of organization / entity

Shahid Sadoughi University of Medical Sciences

Full name of responsible person

Fatemeh Modjallal Najjar

Position

Medical Doctor , Emergency Medicine Resident

Other areas of specialty/work

Street address

Shahid Sadoughi University of Medical Sciences, Shahid Bahonar Sq.

City

Yazd

Postal code

۸۹۱۶۹۷۸۴۷۷

Phone

+98 35 3823 5055

Fax**Email**

fmodjallal@yahoo.com,fmodjallal@ssu.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