

# Clinical Trial Protocol

## Iranian Registry of Clinical Trials

19 Jul 2026

### Evaluating the effect of Tranexamic acid on brain contusion and intracerebral hemorrhage in patients with traumatic brain injury (TBI)

#### Protocol summary

##### Study aim

Evaluating the effect of Tranexamic acid on brain contusion and intracerebral hemorrhage in patients with traumatic brain injury (TBI)

##### Design

A clinical trial with the control group, with parallel groups, double-blind, randomized, phase 3 on 80 patients

##### Settings and conduct

This study is a randomized clinical trial that will be performed in Kashan's Shahid Beheshti Hospital. 40 patients in each group, receiving tranexamic acid and control, will be evaluated. In order to blind the study, syringes containing tranexamic acid and normal saline, will be drawn, coded by one of the colleagues and provided to the nurses of the relevant wards to inject into the patients under study, based on random blocking. None of the physicians or nurses were aware of the type of medication used for the patients

##### Participants/Inclusion and exclusion criteria

Inclusion criteria: All patients over 13 years of age with blunt traumatic brain injury referred to the emergency department who have been less than 3 hours from the time of the accident to the arrival and have cerebral hemorrhage on CT scan. Exclusion criteria: Major organ damage requiring surgical intervention during the first 3 hours, Taking any medication that interferes with homeostasis.

##### Intervention groups

Intervention group: Tranexamic acid drug, produced by Iran Daroo company, IR Iran, is infused with the initial dose of 1 g per 100 ml of serum within 10 minutes and then with a dose of 1 g per 1000 ml of serum for 8 hours, as maintenance dose. Control group: Placebo, containing normal saline serum produced by Iran Daroo Co, IR Iran, is infused with an initial dose of 1 gr in 100 cc normal saline in 10 minutes and continued with dose of 1 gr in 1000 cc in 8 hours as maintenance dose.

##### Main outcome variables

Brain contusion and intracerebral hemorrhage

#### General information

##### Reason for update

##### Acronym

##### IRCT registration information

IRCT registration number: **IRCT20190422043339N1**

Registration date: **2021-12-03, 1400/09/12**

Registration timing: **retrospective**

Last update: **2021-12-03, 1400/09/12**

Update count: **0**

##### Registration date

2021-12-03, 1400/09/12

##### Registrant information

##### Name

Voorya Nouranipour

##### Name of organization / entity

##### Country

Iran (Islamic Republic of)

##### Phone

+98 31 5554 0026

##### Email address

voorya.nooranipoor.1990@gmail.com

##### Recruitment status

**Recruitment complete**

##### Funding source

##### Expected recruitment start date

2018-09-23, 1397/07/01

##### Expected recruitment end date

2020-03-19, 1398/12/29

##### Actual recruitment start date

empty

##### Actual recruitment end date

empty

##### Trial completion date

empty

**Scientific title**  
Evaluating the effect of Tranexamic acid on brain contusion and intracerebral hemorrhage in patients with traumatic brain injury (TBI)

**Public title**  
the effect of hemorrhage preventing medication

**Purpose**  
Treatment

**Inclusion/Exclusion criteria**  
**Inclusion criteria:**  
All patients over 13 years of age with blunt traumatic brain injury were referred to the emergency department less than 3 hours after the accident. Patients on CT scan have cerebral intraparenchymal hemorrhage upon arrival.  
**Exclusion criteria:**  
Major damage to organs requiring surgical intervention within the first 3 hours Get any medication that disrupts homeostasis

**Age**  
From **13 years** old

**Gender**  
Both

**Phase**  
3

**Groups that have been masked**

- Participant
- Care provider

**Sample size**  
Target sample size: **80**

**Randomization (investigator's opinion)**  
Randomized

**Randomization description**  
Random allocation of patients (randomization unit is "person") into two groups of 40 people was performed using a random quadruple block method, that is done through the website: [www.sealedenvelope.com](http://www.sealedenvelope.com). In each of the 20 quadruple blocks, 2 patients will receive medication (tranexamic acid) and 2 patients will receive placebo (normal saline). It should be noted that this study is a three-blind study in which physicians and nurses, patients and analyst will be unaware of patient groups.

**Blinding (investigator's opinion)**  
Double blinded

**Blinding description**  
In order to blind the study, syringes containing tranexamic acid and normal saline were pre-drawn, coded, and delivered to the nurses of the relevant wards to inject into the patients under study based on random blocking. None of the physicians and nurses knew the type of medication used for the patients and only one of the implementers of the project knew the medication's code, so that in case of any problem or complication for the patients, he/she would break the medication's code and inform the relevant physician.

**Placebo**  
Used

**Assignment**  
Parallel

**Other design features**

**Secondary Ids**  
empty

**Ethics committees**

1

**Ethics committee**  
**Name of ethics committee**  
Ethics committee of Kashan University of Medical Sciences  
**Street address**  
School of Medicine, Nurse Blvd., Qotb Ravandi Blvd.  
**City**  
Kashan  
**Province**  
Isfahan  
**Postal code**  
8715981151

**Approval date**  
2019-03-06, 1397/12/15

**Ethics committee reference number**  
IR.KAUMS.MEDNT.REC.1398.004

## Health conditions studied

1

**Description of health condition studied**  
intracranial hematoma and contusion

**ICD-10 code**  
S06.3

**ICD-10 code description**  
Focal traumatic brain injury

## Primary outcomes

1

**Description**  
Brain contusion

**Timepoint**  
At baseline, 24 and 48 hours after injection

**Method of measurement**  
Brain CT scanning

2

**Description**  
intracerebral hemorrhage

**Timepoint**  
At baseline, 24 and 48 hours after injection

**Method of measurement**  
Brain CT scanning

## Secondary outcomes

empty

## Intervention groups

1

### Description

Intervention group: Tranexamic acid made in Iran and Iran Daru Pharmaceutical Company is infused with an initial dose of 1 g per 100 ml of serum within 10 minutes and then infused with a 1 g per 1000 ml maintenance dose of serum for 8 hours.

### Category

Treatment - Drugs

2

### Description

Control group: The placebo group was infused with normal saline made in Iran and Iran Daru Pharmaceutical Company with an initial dose of 1 g per 100 ml of serum within 10 minutes and then infused with a maintenance dose of 1 g per 1000 ml of serum for 8 hours.

### Category

Treatment - Drugs

## Recruitment centers

1

### Recruitment center

#### Name of recruitment center

Shahid Beheshty Hospital

#### Full name of responsible person

Esmaeel Fakharian

#### Street address

Shahid Beheshty Hospital-Nurse Blvd-Qotb Ravandi BLVD

#### City

Kashan

#### Province

Isfahan

#### Postal code

8715981151

#### Phone

+98 31 5554 0026

#### Email

fakharian.es@gmail.com

## Sponsors / Funding sources

1

### Sponsor

#### Name of organization / entity

Kashan University of Medical Sciences

#### Full name of responsible person

Hamidreza Banafsheh

#### Street address

Kashan University of Medical Science, Qotb Ravandi

Blvd

#### City

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#### Province

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#### Postal code

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#### Phone

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#### Email

banafshe57@hotmail.com

### Grant name

### Grant code / Reference number

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

Yes

### Title of funding source

Kashan 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

Kashan University of Medical Sciences

#### Full name of responsible person

Esmaeel Fakharian

#### Position

Professor

#### Latest degree

Specialist

#### Other areas of specialty/work

Neurosurgery

#### Street address

No.12-Shahed Alley-Shahid Beheshty Avenue-Kashan

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#### Phone

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#### Email

efakharian@gmail.com

## Person responsible for scientific inquiries

### Contact

#### Name of organization / entity

Kashan University of Medical Sciences

**Full name of responsible person**

Esmaeel Fakharian

**Position**

Professor

**Latest degree**

Specialist

**Other areas of specialty/work**

Neurosurgery

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**Sharing plan****Deidentified Individual Participant Data Set (IPD)**

Yes - There is a plan to make this available

**Study Protocol**

Yes - There is a plan to make this available

**Statistical Analysis Plan**

Yes - There is a plan to make this available

**Informed Consent Form**

Yes - There is 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**

Yes - There is a plan to make this available

**Title and more details about the data/document**

Part of the data can be shared.

**When the data will become available and for how long**

The data will be available, three months after the publication.

**To whom data/document is available**

Academic researchers, physicians, and medical students, and treatment staff personnel

**Under which criteria data/document could be used**

Use to improve the treatment process of patients and to plan the same projects

**From where data/document is obtainable**

Dr.Esmaeel Fakharian Neurosurgery ward, Shahid Beheshti Hospital, Qotbe ravandi BLVD, Kashan Tel: 00983155540026 efakharian@gmail.com

**What processes are involved for a request to access data/document**

The request will be sent by email, after survey.

**Comments****Person responsible for updating data****Contact****Name of organization / entity**

Kashan University of Medical Sciences

**Full name of responsible person**

Voorya Nouranipoor

**Position**

Resident

**Latest degree**

Medical doctor

**Other areas of specialty/work**

Neurosurgery

**Street address**

Shahid Beheshti University Hospital-Qotb Ravandi BLVD

**City**

Kashan

**Province**

Isfahan

**Postal code**