

# Clinical Trial Protocol

## Iranian Registry of Clinical Trials

13 Jun 2026

### The effect of tranexamic acid in reducing mortality and the need for blood transfusion in trauma patients with significant bleeding

#### Protocol summary

##### Summary

Objective: To define effect of Tranexamic Acid on reducing the mortality rate and blood transfusion requirements in trauma patients with significant bleeding. Design: Randomized, double-blind, placebo-controlled trial. Setting and conduct: 60 traumatic patients meeting inclusion and exclusion criteria were selected and randomly assigned into two groups. For the intervention group, 1000 mg Tranexamic Acid in 100 ml of normal saline was infused in 10 minutes in the first 8 hours of trauma occurrence then 1 gr was infused every 8 hours. control group received normal saline with distilled water. Results were compared between groups. Inclusion criteria were age > 5 years; Systolic blood pressure < 90 mmHg; Heart rate > 110; no indication for surgery. Interventions: intervention and control groups received Tranexamic acid and placebo respectively. The main outcome variables: Primary outcomes are the rate of mortality and need for blood transfusions were primary outcomes and hospitalization days in intensive care unit, organ failure and the incidence of thromboembolic complications were secondary outcome.

#### General information

##### Acronym

##### IRCT registration information

IRCT registration number: **IRCT2016040816473N6**

Registration date: **2016-05-29, 1395/03/09**

Registration timing: **retrospective**

Last update:

Update count: **0**

##### Registration date

2016-05-29, 1395/03/09

##### Registrant information

Name

Farzad Kakaei

##### Name of organization / entity

Tabriz University of Medical Sciences

##### Country

Iran (Islamic Republic of)

##### Phone

+98 41 1334 1317

##### Email address

fkakaei@tbzmed.ac.ir

##### Recruitment status

**Recruitment complete**

##### Funding source

tabriz university of medical science

##### Expected recruitment start date

2014-12-22, 1393/10/01

##### Expected recruitment end date

2015-12-22, 1394/10/01

##### Actual recruitment start date

empty

##### Actual recruitment end date

empty

##### Trial completion date

empty

##### Scientific title

The effect of tranexamic acid in reducing mortality and the need for blood transfusion in trauma patients with significant bleeding

##### Public title

The effect of tranexamic acid in reducing mortality and the need for blood transfusion in trauma patients with significant bleeding

##### Purpose

Treatment

##### Inclusion/Exclusion criteria

Inclusion criteria: age > 5 years; Systolic blood pressure < 90 mmHg; Heart rate > 110; no indication for surgery

##### Age

No age limit

**Gender**

Both

**Phase**

2-3

**Groups that have been masked**

No information

**Sample size**

Target sample size: 60

**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 Tabriz university of medical science

**Street address**

Golgasht St, Azadi St

**City**

Tabriz

**Postal code**

**Approval date**

2015-07-27, 1394/05/05

**Ethics committee reference number**

TBZMED.REC.1394.492

**Health conditions studied**

1

**Description of health condition studied**

Tranexamic acid

**ICD-10 code**

Y44.3

**ICD-10 code description**

Anticoagulant antagonists, vitamin K and other coagulants

2

**Description of health condition studied**

transfusion

**ICD-10 code**

Z51.3

**ICD-10 code description**

Blood transfusion (without reported diagnosis)

**Primary outcomes**

1

**Description**

Mortality

**Timepoint**

From admission until discharge or death, and a maximum of one month after hospitalization

**Method of measurement**

via clinical records

2

**Description**

Need for blood transfusion

**Timepoint**

From admission until discharge or death, and a maximum of one month after hospitalization

**Method of measurement**

via clinical records

**Secondary outcomes**

1

**Description**

Hospitalization days in ICU

**Timepoint**

From admission until discharge or death, and a maximum of one month after hospitalization

**Method of measurement**

via clinical records

2

**Description**

Organ Failure

**Timepoint**

From admission until discharge or death, and a maximum of one month after hospitalization

**Method of measurement**

via clinical records

3

**Description**

Thrombotic complications

**Timepoint**

From admission until discharge or death, and a maximum of one month after hospitalization

**Method of measurement**

via clinical records

**Intervention groups**

1

**Description**

In case group: Tranexamic acid infusion

**Category**

Treatment - Drugs

**2****Description**

In control group: placebo infusion

**Category**

Treatment - Drugs

**Recruitment centers****1****Recruitment center****Name of recruitment center**

Imam Reza Education, Treatment and Research Center

**Full name of responsible person**

Farzad Kakaei

**Street address**

Golgashst St, Azadi St

**City**

Tabriz

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

Vice chancellor for research, Tabriz University of Medical Sciences

**Full name of responsible person**

Mohammad Reza Rashidi

**Street address**

Tabriz University of Medical Science, Golgasht St, Azadi St

**City**

Tabriz

**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, Tabriz 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**

Tabriz University of Medical Sciences

**Full name of responsible person**

Farzad Kakaei

**Position**

General Surgeon/ Associate Professor

**Other areas of specialty/work****Street address**

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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*