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 wereage>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

Mortallity

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
Golgasht 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
Imam Reza Education, Treatment and Research Centerl, Golgasht St, Azadi St
City
Tabriz
Postal code
Phone
+98 41 3334 1317
Fax
Email
fkakaei@tbzmed.ac.ir
Web page address

Person responsible for scientific inquiries

Contact
Name of organization / entity
Tabriz University of Medical Sciences
Full name of responsible person
Farzad Kakaei
Position
General Surgeon
Other areas of specialty/work
Street address
Imam Reza Education, Treatment and Research Center, Golgasht St, Azadi St
City
Tabriz
Postal code
Phone
+98 41 3334 1317
Fax
Email
fkakaei@tbzmed.ac.ir
Web page address

Person responsible for updating data

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
Imam Reza Education, Treatment and Research Centerl, Golgasht St, Azadi St
City
Tabriz

Postal code

Phone

+98 41 3334 1317

Fax

Email

fkakaei@tbzmed.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