

Clinical Trial Protocol

Iranian Registry of Clinical Trials

20 Jul 2026

Evaluation safety and efficiency of early administration of Tranexamic acid in trauma patient

Protocol summary

Study aim

Determining the rate of mortality in patients with early administration of tranexamic acid
Determining the rate of hemoglobin decrease in patients with early administration of tranexamic acid
Determining the rate of blood transfusion in patients with early administration of tranexamic acid
Determining the rate of mortality in control group of patients
Determining the rate of hemoglobin decrease in control group of patients
Determining the rate of blood transfusion in control group of patients
Comparison of death rate in patients with early administration of tranexamic acid and control group
Comparison of hemoglobin decrease in patients with early administration of tranexamic acid and control group
Comparison of blood transfusion in patients with early administration of tranexamic acid and control group

Design

Clinical trial with control group, blinded, randomised, phase 3 on 66 patients.

Settings and conduct

Multiple trauma patients admitted in emergency department of Ayatollah Mousavi hospital with ABC trauma score more than 2 will be divided randomized in 2 groups. 1gr Tranexamic acid will be infused in 10 minutes to intervention group and Normal Saline will be infused in Control Group.

Participants/Inclusion and exclusion criteria

Inclusion criteria: - Referred to Ayatollah Mousavi Hospital in Zanjan due to trauma in 1400 - Gender of men and women - Age over 15 years - More than 2 points in the ABC scoring system
Exclusion criteria: - Pregnancy - Renal failure - Coagulopathy - Acute brain injuries - Consumption of anticoagulants

Intervention groups

Traumatic patients will be divided in two groups of receiving Tranexamic Acid containing serum and Normal Saline as placebo.

Main outcome variables

Comparison of mortality, hemoglobin decrease and blood transfusion in intervention and control groups of patients.

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20220507054758N1**

Registration date: **2022-05-24, 1401/03/03**

Registration timing: **prospective**

Last update: **2022-05-24, 1401/03/03**

Update count: **0**

Registration date

2022-05-24, 1401/03/03

Registrant information

Name

Amin Esfandyari

Name of organization / entity

Country

Iran (Islamic Republic of)

Phone

+98 41 3443 2869

Email address

aminesf1369@gmail.com

Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2022-06-05, 1401/03/15

Expected recruitment end date

2023-06-05, 1402/03/15

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date
empty

Scientific title
Evaluation safety and efficiency of early administration of Tranexamic acid in trauma patient

Public title
Evaluation safety and efficiency of early administration of Tranexamic acid in trauma patient

Purpose
Treatment

Inclusion/Exclusion criteria
Inclusion criteria:
All patients admitted with multiple trauma over than 15 years old with ABC trauma score more than 2 scores patient satisfaction to study
Exclusion criteria:
pregnancy brain injuries coagulopathy renal failure using anticoagulants

Age
From **15 years** old

Gender
Both

Phase
3

Groups that have been masked

- Participant

Sample size
Target sample size: **66**

Randomization (investigator's opinion)
Not randomized

Randomization description

Blinding (investigator's opinion)
Single blinded

Blinding description
Control group patients will receive normal saline serum which shape and injection is the same as the drug(tranexamic acid).

Placebo
Used

Assignment
Single

Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee
Name of ethics committee
Ethics committee of Zanjan University of Medical Sciences
Street address
Ayatollah Mousavi hosp. Gavazang Blvd. Zanjan
City

Zanjan
Province
Zanjan
Postal code
4513956183
Approval date
2022-10-30, 1401/08/08
Ethics committee reference number
IR.ZUMS.REC.1401.044

Health conditions studied

1

Description of health condition studied
Trauma
ICD-10 code
ICD-10 code description

Primary outcomes

1

Description
Mortality
Timepoint
All days of hospital admission
Method of measurement
Discharge or death of patient

2

Description
Hemoglobin decrease
Timepoint
All days of hospital admission
Method of measurement
Hemoglobin in laboratory data

3

Description
Blood transfusion
Timepoint
All days of hospital admission
Method of measurement
Evaluate patient records

Secondary outcomes

empty

Intervention groups

1

Description
Intervention group: Patients who receive 1 gram Tranexamic Acid during 10 minutes intravenous infusion
Category
Treatment - Drugs

2

Description

Control group: Patients who receive intravenous infusion of Normal Saline during 10 minutes with the same volume of Tranexamic Acid containing serum in intervention group.

Category

Placebo

Recruitment centers

1

Recruitment center

Name of recruitment center

Zanjan Ayatollah Mousavi Hospital

Full name of responsible person

Amin Esfandyari Kalajahi

Street address

Ayatollah Mousavi Hospital. Gavazang blvd. Zanjan

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4513956183

Phone

+98 24 3313 0000

Email

Mousavihospital@zums.ac.ir

Web page address

<https://mousavi.zums.ac.ir/>

Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Zanjan University of Medical Sciences

Full name of responsible person

Ali Ammari

Street address

Ayatollah Mousavi hospital. Gavazang blvd. Zanjan

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Email

Mousavihospital@zums.ac.ir

Web page address

<https://mousavi.zums.ac.ir/>

Grant name

Grant code / Reference number

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

No

Title of funding source

Zanjan Ayatollah Mousavi hospital

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

Zanjan University of Medical Sciences

Full name of responsible person

Amin Esfandyari

Position

Resident

Latest degree

Medical doctor

Other areas of specialty/work

General Surgery

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Kavazang s. Ayatollah mousavi hosp.

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Person responsible for scientific inquiries

Contact

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Person responsible for updating data

Contact

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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

No - There is not a plan to make this available

Title and more details about the data/document

Mechanism of trauma, death or discharge, Hemoglobin changes, blood transfusion

When the data will become available and for how long

1 year after publish

To whom data/document is available

Researchers of academic institutions

Under which criteria data/document could be used

All data on the condition that personal information of patients must be preserved and the person in charge of this project mentioned in the study.

From where data/document is obtainable

Email to Amin Esfandyari Kalajahi,
Aminesf1369@gmail.com

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

After sending the proposal of study and to guarantee that the person in charge of this project mentioned in the study.

Comments