Clinical Trial Protocol
Iranian Registry of Clinical Trials

18 Sep 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 trail 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 divided randomized in 2 groups.1gr Tranexamic acid will be infused in 10minutes to intervention group and Normal Slain 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 coaglopathy renal failure using anticoaglants

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

Ayatollam 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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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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Web page address
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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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Person responsible for updating data

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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