Clinical Trial Protocol
Iranian Registry of Clinical Trials

27 Jun 2026

Comparative of effectiveness prehospital received tranexamic acid on transmission blood volume on severe trauma patients

Protocol summary

Study aim

The purpose of this study was to investigate the effect of tranexamic acid in traumatic injuries in order to have its effect on reducing the need for blood transfusion or its products, mortality and reduction of hospitalization in intensive care unit.

Design

This study was a parallel randomized controlled clinical trial study design. The sample size of the study is 330 traumatic patients that will be assigned to intervention and control groups using block randomization method.

Settings and conduct

To reduce blood transfusion and its products in traumatic patients who needed, tranexamic acid will be prescribed by the prehospital emergency in the scene and infusion dose will be performed at Rasoul Akram and Shohadaye Haftom -e-Tir Hospitals of Iran University of Medical Sciences. To evaluate the effect of tranexamic acid on blood transfusion, mortality and length of stay in intensive care unit for up to 24 hours after admission. Study participants, physicians that assessing the outcomes and Data analyzer will be blind to the type of interventions that patients received.

Participants/Inclusion and exclusion criteria

Traumatic patients in the age range of 14-50 years with a COAST score above two will be included in the study. In addition, more than three hours after the accident are the main exclusion criteria.

Intervention groups

The intervention group will be received tranexamic acid in the initial dose of one gram of 50 milliliter normal saline within 10 minutes (once only), along with other prehospital treatment processes. In this group, the maintenance dose infusion of one gram per 100 milliliter will continue in the hospital for eight hours (up to 24 hours in three stages). The control group will not be used it and only the therapeutic processes required for patients will be performed.

Main outcome variables

Blood transfusion or products, mortality, length of stay in intensive care unit

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20140528017891N7**
Registration date: **2019-11-24, 1398/09/03**
Registration timing: **registered_while_recruiting**

Last update: **2019-11-24, 1398/09/03**
Update count: **0**

Registration date

2019-11-24, 1398/09/03

Registrant information

Name
Nader Tavakoli
Name of organization / entity
Iran University Of Medical Science
Country
Iran (Islamic Republic of)
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+98 21 8891 5410
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tavakoli.n@iums.ac.ir

Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2019-11-16, 1398/08/25

Expected recruitment end date

2020-12-30, 1399/10/10

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Comparative of effectiveness prehospital received tranexamic acid on transmission blood volume on severe trauma patients

Public title

Tranexamic acid effect on blood volume transmission

Purpose

Treatment

Inclusion/Exclusion criteria

Inclusion criteria:

Being at the age of 14-50 Having COAST score more than 2 Bring up to hospital by Tehran emergency medical service

Exclusion criteria:

Passing 3 hours from trauma Having signs of Disseminated intravascular coagulation, myocardial infarction, pulmonary embolism, Stroke Warning Signs and Symptoms Allergic reaction

Age

From **14 years** old to **50 years** old

Gender

Both

Phase

3

Groups that have been masked

- Participant
- Outcome assessor
- Data analyser

Sample size

Target sample size: **330**

Randomization (investigator's opinion)

Randomized

Randomization description

For prevention of selection bios in participants into study groups,we use the randomization methods.Ranom Alloction software will be used for randomization process.Participants will be randomized with blocked randomizationmethod(with random blocks) to recieve drug(inervention).The output of allocation will be specified with A and B for being blind to the research team. In this process,allocated participants in accordance with basic blocks are not predictable.

Blinding (investigator's opinion)

Triple blinded

Blinding description

We will inform the supervisor after selecting each patient.Blinding process in this study is triple blinded. They are selected on the randomized output and Its adaption to the participant's number.Blinding process in this study is triple blinded.The intervention will be sent in a form that is not known to the patient statistical analysor and evaluator of the outcomes to decrease the rate of information bios in intervention and outcome valiables.

Placebo

Not used

Assignment

Parallel

Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee

Ethics committee of Iran university of Medical Sciences

Street address

بزرگراه همت، دانشگاه علوم پزشکی ایران

City

Tehran

Province

Tehran

Postal code

1449614535

Approval date

2019-08-17, 1398/05/26

Ethics committee reference number

IR.IUMS.REC.1398.477

Health conditions studied

1

Description of health condition studied

Bleeding in trauma

ICD-10 code

T14.5

ICD-10 code description

Injury of blood vessel(s) of unspecified body region

Primary outcomes

1

Description

Bleeding control

Timepoint

Up to 24 hours after admission to hospital

Method of measurement

Get blood products

2

Description

Mortality

Timepoint

Up to 24 hours after admission to hospital

Method of measurement

Vital signs observation in patient

Secondary outcomes

1

Description
Length time in intensive care unit
Timepoint
The number of days the patient is in intensive care
Method of measurement
Counting the days when the patient was in the ward

Intervention groups

1

Description
Intervention group: They will receive tranexamic acid at an initial dose of one gram of 50 milliliter normal saline within 10 minutes (only once), along with other prehospital treatment processes. In addition, the infusion of a maintenance dose of 1 germ per 100 milliliter will continue in the hospital for eight hours (up to 24 hours in three stages).
Category
Treatment - Drugs

2

Description
Control group: In this group placebo will not be used and only the treatment processes required for the patients will be performed.
Category
Treatment - Drugs

Recruitment centers

1

Recruitment center
Name of recruitment center
Rasoul Akram hospital
Full name of responsible person
Nader Tavakoli
Street address
Rasoul Akram hospital, Niyayesh St, Sattarkhan St
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Tehran
Postal code
1445613131
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2

Recruitment center
Name of recruitment center
Shohadaye Haftom -e-Tir
Full name of responsible person
Nader Tavakoli
Street address
South Shahid Rajaee Highway
City
Tehran
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Postal code
1886718136
Phone
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Sponsors / Funding sources

1

Sponsor
Grant name
Grant code / Reference number
Is the source of funding the same sponsor organization/entity?
empty
Title of funding source
Proportion provided by this source
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

2

Sponsor
Name of organization / entity
Tehran Emergency Center
Full name of responsible person
Peyman Saberian
Street address
No. 58, Tehran Emergency Center, Sharif Alley, South Iranshahr Ave.
City
Tehran
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Tehran
Postal code
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Phone
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Fax
+98 21 4923 1000
Email

research@tehran115.ir

Grant name

Grant code / Reference number

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

Yes

Title of funding source

Tehran Emergency Center

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

Other

Person responsible for general inquiries

Contact

Name of organization / entity

Iran University of Medical Sciences

Full name of responsible person

Nader Tavakoli

Position

Association

Latest degree

Specialist

Other areas of specialty/work

Emergency Medicine

Street address

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Person responsible for scientific inquiries

Contact

Name of organization / entity

Iran University of Medical Sciences

Full name of responsible person

Nader Tavakoli

Position

Association

Latest degree

Specialist

Other areas of specialty/work

Emergency Medicine

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Person responsible for updating data

Contact

Name of organization / entity

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Position

Association

Latest degree

Specialist

Other areas of specialty/work

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Email

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Sharing plan

Deidentified Individual Participant Data Set (IPD)

Undecided - It is not yet known if there will be a plan to make this available

Study Protocol

Undecided - It is not yet known if there will be a plan to make this available

Statistical Analysis Plan

Undecided - It is not yet known if there will be a plan to make this available

Informed Consent Form

Undecided - It is not yet known if there will be a plan to make this available

Clinical Study Report

Yes - There is a plan to make this available

Analytic Code

Undecided - It is not yet known if there will be a plan to make this available

Data Dictionary

Undecided - It is not yet known if there will be a plan to make this available

Title and more details about the data/document

Findings of the study, demographic data of participants in the study, in addition to descriptive and analytical analysis of variables.

When the data will become available and for how long

Availability eight months after the end of study

To whom data/document is available

Specialists of emergency medicine and prehospital emergency

Under which criteria data/document could be used

In the case of comparison with other similar trials or treatmen

From where data/document is obtainable

Iran University of Medical Sciences and Tehran emergency center

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

By referring to the central library and clinical trial center in Iran University of Medical Sciences can access to the documents of participants, data and results.

Comments