

# 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)

##### Phone

+98 21 8891 5410

##### Email address

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 bias in participants into study groups, we use the randomization methods. Ranom Allocation software will be used for randomization process. Participants will be randomized with blocked randomization method (with random blocks) to receive drug (intervention). 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 adaptation 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 analyst and evaluator of the outcomes to decrease the rate of information bias in intervention and outcome variables.

**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

##### City

Tehran

##### Province

Tehran

##### Postal code

1445613131

##### Phone

+98 21 6653 9260

##### Fax

+98 21 6653 9233

##### Email

tavakoli.n@iums.ac.ir

### 2

#### Recruitment center

##### Name of recruitment center

Shohadaye Haftom -e-Tir

##### Full name of responsible person

Nader Tavakoli

##### Street address

South Shahid Rajaei Highway

##### City

Tehran

##### Province

Tehran

##### Postal code

1886718136

##### Phone

+98 21 6653 9260

##### Fax

+98 21 6653 9233

##### Email

tavakoli.n@iums.ac.ir

## 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

##### Province

Tehran

##### Postal code

1581615117

##### Phone

+98 21 4923 1000

##### Fax

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##### 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

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## Person responsible for scientific inquiries

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## Person responsible for updating data

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**Full name of responsible person**

Nader Tavakoli

**Position**

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**Latest degree**

Specialist

**Other areas of specialty/work**

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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 treatment

**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**