

# Clinical Trial Protocol

## Iranian Registry of Clinical Trials

05 Jun 2026

### The effect of intravenous Tranexamic acid on postoperative bleeding in patients with shaft femoral fractures

#### Protocol summary

##### Study aim

Evaluation effect of intravenous Tranexamic acid on postoperative bleeding in patients with shaft femoral fractures

##### Design

The study will be double blind and clinical trial. 60 patients will be randomly divided into 2 groups. The groups are parallel. The trial phase is 3

##### Settings and conduct

Patients candidate for surgery of shaft femoral fractures in Valiasr Hospital in Arak are divided into 2 groups by simple randomization with blocks. The study is double-blind in which outcome evaluator and data analyst and participant are kept blind.

##### Participants/Inclusion and exclusion criteria

Inclusion criteria: All patients who are candidates for shaft and distal femoral fractures, lack of sensitivity to tranexamic acid, surgery that lasts less than 3 hours  
Exclusion criteria: underlying diseases such as kidney disease, history of myocardial ischemia, hypertension, history of cerebral ischemia, history of thromboembolism, anemia, take any anticoagulants for 5 days before surgery, hematuria, platelets less than 150,000 before surgery

##### Intervention groups

In the intervention group, before the start of surgery, 10 milligram in kilogram of tranexamic acid (Tranexip in Iran -Caspian Company, 100 milligram in kilogram) will be given by slow intravenous injection with vital signs and standard monitoring careful control. In the control group, they will receive the same amount intravenously before starting placebo surgery (normal saline).

##### Main outcome variables

Bleeding amount, hemoglobin amount, hematocrit amount, mortality

#### General information

##### Reason for update

##### Acronym

##### IRCT registration information

IRCT registration number: **IRCT20211208053326N1**  
Registration date: **2022-01-30, 1400/11/10**  
Registration timing: **registered\_while\_recruiting**

Last update: **2022-01-30, 1400/11/10**

Update count: **0**

##### Registration date

2022-01-30, 1400/11/10

##### Registrant information

##### Name

Rahim Shiri

##### Name of organization / entity

##### Country

Iran (Islamic Republic of)

##### Phone

+98 86 3417 4553

##### Email address

raminshiri45@gmail.com

##### Recruitment status

**Recruitment complete**

##### Funding source

##### Expected recruitment start date

2022-01-20, 1400/10/30

##### Expected recruitment end date

2023-01-20, 1401/10/30

##### Actual recruitment start date

empty

##### Actual recruitment end date

empty

##### Trial completion date

empty

##### Scientific title

The effect of intravenous Tranexamic acid on postoperative bleeding in patients with shaft femoral fractures

## Public title

The effect of intravenous Tranexamic acid on postoperative bleeding in patients with shaft femoral fractures

## Purpose

Treatment

## Inclusion/Exclusion criteria

### Inclusion criteria:

All patients who are candidates for shaft and distal femoral fractures  
Lack of sensitivity to tranexamic acid  
No history of cerebral ischemia  
Lack of hematuria  
Surgery that lasts less than 3 hours

### Exclusion criteria:

hypertension  
history of cerebral ischemia  
anemia  
take any anticoagulants for 5 days before surgery  
platelets less than 150,000 before surgery  
history of myocardial ischemia  
underlying diseases such as kidney disease

## Age

No age limit

## Gender

Both

## Phase

2-3

## Groups that have been masked

- Participant
- Outcome assessor
- Data analyser

## Sample size

Target sample size: 60

## Randomization (investigator's opinion)

Randomized

## Randomization description

Patients will be allocated into 3 groups using a permuted balanced block randomization method with the size of blocks 4 and 8. Random sequence will be generated by an epidemiologist by running an online program in sealed envelope website (<https://www.sealedenvelope.com/>). Random chain concealment is done by opaque envelope method.

## Blinding (investigator's opinion)

Double blinded

## Blinding description

The study is double-blind. The analysis is done by the analyzer and outcome evaluator and the participant. analyzer, evaluators, and participants are unaware of the consequences of grouping. The Resident is unaware of the drugs prescribed in each group and the orthopedic specialist prescribes the drug. Patients also do not know their group.

## Placebo

Used

## Assignment

Parallel

## Other design features

## Secondary Ids

empty

## Ethics committees

### 1

#### Ethics committee

##### Name of ethics committee

Ethics committee of Arak University of Medical Sciences

##### Street address

Ethics committee, Research center, Payambar Azam complex, Basij square, Sardasht, Arak

##### City

Arak

##### Province

Markazi

##### Postal code

3848176941

#### Approval date

2021-11-17, 1400/08/26

#### Ethics committee reference number

IR.ARAKMU.REC.1400.233

## Health conditions studied

### 1

#### Description of health condition studied

shaft femoral fractures

#### ICD-10 code

S72.3

#### ICD-10 code description

Fracture of shaft of femur

## Primary outcomes

### 1

#### Description

Bleeding amount

#### Timepoint

From 6 hours and 24 hours after surgery

#### Method of measurement

Millilitre

### 2

#### Description

Hemoglobin amount

#### Timepoint

Before and after surgery

#### Method of measurement

Blood test

### 3

#### Description

Hematocrit amount

#### Timepoint

Before and after surgery

#### Method of measurement

Blood test

#### 4

**Description**

Mortality

**Timepoint**

End of study

**Method of measurement**

Observation

**Secondary outcomes**

empty

**Intervention groups**

#### 1

**Description**

Intervention group: Before the start of surgery, 10 milligram in kilogram of tranexamic acid (Tranexip in Iran -Caspian Company, 100 milligram in kilogram) will be given by slow intravenous injection with vital signs and standard monitoring careful control.

**Category**

Treatment - Drugs

#### 2

**Description**

Control group: In the control group, they will receive the same amount intravenously before starting placebo surgery (normal saline).

**Category**

Treatment - Drugs

**Recruitment centers**

#### 1

**Recruitment center****Name of recruitment center**

Valiasr hospital

**Full name of responsible person**

Dr Mohsen Parsi khameneh

**Street address**

Valiasr hospital, Valiasr squire

**City**

Arak

**Province**

Markazi

**Postal code**

3848176941

**Phone**

+98 86 3222 2003

**Email**

parsi70@yahoo.com

**Sponsors / Funding sources**

#### 1

**Sponsor****Name of organization / entity**

Arak University of Medical Sciences

**Full name of responsible person**

Dr Alireza Kamali

**Street address**

Research Center, Payambar Azam Complex, Basij square, Sardasht, Arak

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alikamaliir@yahoo.com

**Grant name****Grant code / Reference number****Is the source of funding the same sponsor organization/entity?**

Yes

**Title of funding source**

Arak University of Medical Sciences

**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**

Arak University of Medical Sciences

**Full name of responsible person**

Dr Mohsen Parsi Kameneh

**Position**

Assistant professor

**Latest degree**

Specialist

**Other areas of specialty/work**

Orthopedics

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Valiasr hospital, Valiasr squire

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## Person responsible for scientific inquiries

### Contact

**Name of organization / entity**

Arak University of Medical Sciences

**Full name of responsible person**

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**Position**

Assistant professor

**Latest degree**

Specialist

**Other areas of specialty/work**

Orthopedics

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## Person responsible for updating data

### Contact

**Name of organization / entity**

Arak University of Medical Sciences

**Full name of responsible person**

Rahim Shiri

**Position**

Rezident

**Latest degree**

Medical doctor

**Other areas of specialty/work**

Orthopedics

**Street address**

Vice chancellor for research, Payambar Azam Complex, Basij square, Sardasht, Arak

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**Fax****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**

Undecided - It is not yet known if there will be 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