

# Clinical Trial Protocol

## Iranian Registry of Clinical Trials

30 Jun 2026

### Study of effect of tranexamic acid on the amount of bleeding during surgery and surgeons satisfaction in intertrochantric fracture

#### Protocol summary

##### Study aim

To determine effect of tranexamic acid on bleeding amount during surgery and surgeon satisfactions in intertrochanteric fracture

##### Design

Clinical trial; Parallel group; Randomized; Double blind

##### Settings and conduct

In one trauma center by one surgeon patients which undergoing internal fixation by plate for intertrochanteric fracture, after randomization put in two group with 31 patients. For every patient records questionnaire including demographic data, medical history, drug history and their side effects, bleeding amounts, using gauze's numbers and surgeon opinion. After spinal anesthesia, in intervention group, 1 gram tranexamic acid ( syringe B) and in control group ,5 milligram normal saline( syringe A) which dilute up to 100 milliliter with normal saline prepare by uninformed nurse and was handed to anesthesiologist that injected via intravenous during 10 minute. As for transparent state of drug,anesthesiologist and surgeon are not informed about injected drug or groups and just they are responsible over filling the questionnaire.

##### Participants/Inclusion and exclusion criteria

Patients with intertrochantric fracture; Age between 60-80 years;Patients with ASA ( American Society of Anesthesiologist ) 0 or 1;

##### Intervention groups

In intervention group, patients with intertrochanteric fracture which undergo internal fixation with plate, during surgery to evaluate effect of tranexamic acid on bleeding amounts and surgeon satisfactions, one gram tranexamic acid was inject and bleeding amounts and surgeon satisfactions was evaluated.

##### Main outcome variables

Age;Sex; Fracture type; bleeding amounts; hemoglobin; surgeon satisfactions;

#### General information

##### Reason for update

##### Acronym

##### IRCT registration information

IRCT registration number: **IRCT20200114046133N1**

Registration date: **2020-02-02, 1398/11/13**

Registration timing: **registered\_while\_recruiting**

Last update: **2020-02-02, 1398/11/13**

Update count: **0**

##### Registration date

2020-02-02, 1398/11/13

##### Registrant information

##### Name

alireza shafiei

##### Name of organization / entity

##### Country

Iran (Islamic Republic of)

##### Phone

+98 87 3886 7021

##### Email address

alireza.shafiee@kums.ac.ir

##### Recruitment status

**Recruitment complete**

##### Funding source

##### Expected recruitment start date

2020-01-21, 1398/11/01

##### Expected recruitment end date

2020-05-20, 1399/02/31

##### Actual recruitment start date

empty

##### Actual recruitment end date

empty

##### Trial completion date

empty

##### Scientific title

Study of effect of tranexamic acid on the amount of bleeding during surgery and surgeons satisfaction in intertrochantric fracture

#### Public title

Study of effect of tranexamic acid on the amount of bleeding and surgeons satisfaction in intertrochantric fracture

#### Purpose

Treatment

#### Inclusion/Exclusion criteria

##### Inclusion criteria:

Patients with intertrochantric fracture Patients with ASA ( American Society of Anesthesiologist ) 0 or 1

##### Exclusion criteria:

Coagulation problems Anticoagulant drugs consumption Stroke Coronary Artery Diseases Hypertension Deep vein thrombosis Pulmonary Embolism Renal disease Seizure

#### Age

From **60 years** old to **80 years** old

#### Gender

Both

#### Phase

3

#### Groups that have been masked

- Participant
- Care provider
- Investigator
- Outcome assessor
- Data analyser

#### Sample size

Target sample size: **62**

#### Randomization (investigator's opinion)

Randomized

#### Randomization description

Randomization performs by random number table which for every patients was assign a three digit code based on random table number. If right-sided digit is 2,3,5,6,9 labelled as group A and another digits labelled as group B.

#### Blinding (investigator's opinion)

Double blinded

#### Blinding description

Patient are blinded to intervention. After spinal anesthesia, in intervention group, 1 gram tranexamic acid ( syringe B) and in control group ,5 milligram normal saline( syringe A) which dilute up to 100 milliliter with normal saline prepare by uninformed nurse and was handed to anesthesiologist that injected via intravenous during 10 minute. As for transparent state of drug,anesthesiologist and surgeon are not informed about injected drug or groups and just they are responsible over filling the questionnaire.in this research the person who collect the data as well as the statistical advisor are not aware of the allocation of group .

#### Placebo

Used

#### Assignment

Parallel

#### Other design features

## Secondary Ids

empty

## Ethics committees

### 1

#### Ethics committee

##### Name of ethics committee

Ethics committee of kermanshah University of Medical Sciences

##### Street address

shahid beheshti blvd, kermanshah town

##### City

kermanshah

##### Province

Kermanshah

##### Postal code

6715847141

#### Approval date

2020-01-18, 1398/10/28

#### Ethics committee reference number

450.IR.KUMS.REC.1398.

## Health conditions studied

### 1

#### Description of health condition studied

Inter trochantric fracture

#### ICD-10 code

#### ICD-10 code description

## Primary outcomes

### 1

#### Description

Bleeding amounts

#### Timepoint

During surgery and 48 hours after surgery

#### Method of measurement

Blood amounts in suction; gauze's number; blood amounts in drain; hemoglobin after 48 hours

### 2

#### Description

Surgeon satisfactions

#### Timepoint

During surgery

#### Method of measurement

Bozarret scale; Likert scale

## Secondary outcomes

empty

## Intervention groups

## 1

### Description

Intervention group: In intertrochanteric fracture which undergo internal fixation by plate, 1 gram tranexamic acid ( syringe B) and in control group ,5 milligram normal saline( syringe A) which dilute up to 100 milliliter with normal saline prepare by uninformed nurse and was handed to anesthesiologist that injected via intravenous during 10 minute.

### Category

Treatment - Drugs

## 2

### Description

Control group: In intertrochanteric fracture which undergo internal fixation by plate, 5 milligram normal saline( syringe A) which dilute up to 100 milliliter with normal saline prepare by uninformed nurse and was handed to anesthesiologist that injected via intravenous during 10 minute. As for transparent state of drug, anesthesiologist and surgeon are not informed about injected drug or groups and just they are responsible over filling the questionnaire.

### Category

Treatment - Drugs

## Recruitment centers

## 1

### Recruitment center

#### Name of recruitment center

Taleghani hospital

#### Full name of responsible person

Morteza saeb

#### Street address

Taleghani hospital, shahid beheshti blvd, kermanshah town

#### City

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#### Province

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#### Postal code

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#### Phone

+98 83 3838 7752

#### Email

Alireza\_shafiei2010@yahoo.com

## Sponsors / Funding sources

## 1

### Sponsor

#### Name of organization / entity

Kermanshah University of Medical Sciences

#### Full name of responsible person

farid najafi

#### Street address

shahid beheshti blvd, kermanshah town

### City

kermanshah

### Province

Kermanshah

### Postal code

6715847141

### Phone

+98 83 3835 7752

### Email

farid\_n32@yahoo.com

### Grant name

### Grant code / Reference number

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

Yes

### Title of funding source

Kermanshah 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

Kermanshah University of Medical Sciences

#### Full name of responsible person

Alireza shafiei

#### Position

resident

#### Latest degree

Medical doctor

#### Other areas of specialty/work

Orthopedics

#### Street address

taleghani hospital, shahid beheshti blvd, kermanshah town

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#### Postal code

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#### Phone

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#### Email

alireza.shafiee@kums.ac.ir

## Person responsible for scientific inquiries

### Contact

#### Name of organization / entity

Kermanshah University of Medical Sciences

**Full name of responsible person**

Alireza shafiei

**Position**

Resident

**Latest degree**

Medical doctor

**Other areas of specialty/work**

Orthopedics

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taleghani hospital, shahid beheshti blvd, kermanshah city

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**Email**

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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**

Yes - There is a plan to make this available

**Title and more details about the data/document**

effect of tranexamic acid on the amount of bleeding during surgery and surgeons satisfaction in intertrochantric fracture data set all collected deidentified IPD are to be shared .

**When the data will become available and for how long**

Starting 6 months after publication , the data will be available for 20 years .

**To whom data/document is available**

The data will be available only for people working in academic institutions .

**Under which criteria data/document could be used**

No type of analyses on the document is allowed .

**From where data/document is obtainable**

The preferred way of communication is via email. alireza\_shafiei2010 @yahoo.com

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

The requests will be discussed and the data would be available in three months .

**Comments****Person responsible for updating data****Contact****Name of organization / entity**

Kermanshah University of Medical Sciences

**Full name of responsible person**

alireza shafiei

**Position**

resident

**Latest degree**

Medical doctor

**Other areas of specialty/work**

Orthopedics

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