

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

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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

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Phone

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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

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Person responsible for scientific inquiries

Contact

Name of organization / entity

Kermanshah University of Medical Sciences

Full name of responsible person

Alireza shafiei

Position

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Latest degree

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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

Street address

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