

Clinical Trial Protocol

Iranian Registry of Clinical Trials

28 May 2026

The effect of intravenous tranexamic acid on bleeding during and after femoral fracture surgeries under general anesthesia

Protocol summary

Summary

The aim of this double-blind study is to evaluate the effect of intravenous tranexamic acid on bleeding in femoral fracture surgery. Participants are 18-65 year old patients candidate for femoral fracture surgery without history of coagulopathy, thrombosis, aspirin use or other antiplatelete drugs during 2 weeks prior to the surgery and NSAIDs use 2 days before surgery. 126 patients divided to two equal groups control and invention. Invention group receive 15 mg/kg intravenous tranexamic acid 5 minutes before skin incision while control group receive placebo. The amount of intraoperative and postoperative bleeding will be evaluated. Tranexamic acid may cause bleeding reduction in invention group.

General information

Acronym

IRCT registration information

IRCT registration number: **IRCT2013100414302N3**

Registration date: **2013-11-01, 1392/08/10**

Registration timing: **registered_while_recruiting**

Last update:

Update count: **0**

Registration date

2013-11-01, 1392/08/10

Registrant information

Name

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Name of organization / entity

Fasa University Of Medical Sceinces

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Recruitment status

Recruitment complete

Funding source

Ahvaz Jundishapur University of Medical Sciences

Expected recruitment start date

2013-03-20, 1391/12/30

Expected recruitment end date

2014-04-21, 1393/02/01

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

The effect of intravenous tranexamic acid on bleeding during and after femoral fracture surgeries under general anesthesia

Public title

The effect of tranexamic acid on bleeding

Purpose

Prevention

Inclusion/Exclusion criteria

Inclusion criteria: writing consent, age 18-65, ASA class 1-2. exclusion criteria: history of coagulopathy, thrombosis, aspirin use or other antiplatelete drugs during 2 weeks prior to the surgery, NSAID use 2 days before surgery.

Age

From **18 years** old to **65 years** old

Gender

Both

Phase

N/A

Groups that have been masked

No information

Sample size

Target sample size: 126

Randomization (investigator's opinion)

Randomized

Randomization description

Blinding (investigator's opinion)

Double blinded

Blinding description

Placebo

Used

Assignment

Parallel

Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee

Jundishapur University of Medical Sciences

Street address

University town, Golestan Blvd

City

Ahvaz

Postal code

Approval date

2011-09-23, 1390/07/01

Ethics committee reference number

ETH-673

Health conditions studied

1

Description of health condition studied

Femoral fracture

ICD-10 code

s72

ICD-10 code description

Fracture of femur

Primary outcomes

1

Description

Bleeding

Timepoint

During surgery till 48 hours after surgery

Method of measurement

Number of pads during surgery and amount of bleeding in drain in postoperative period

Secondary outcomes

1

Description

Number of received packed cells

Timepoint

During surgery till 48 hours after surgery

Method of measurement

Number of packed cell

Intervention groups

1

Description

Injection of 15 mg/kg intravenous tranexamic 5 min before skin incision in intervention group.

Category

Treatment - Drugs

2

Description

Injection of 15 mg/kg intravenous normal saline 5 min before skin incision in control group.

Category

Treatment - Drugs

Recruitment centers

1

Recruitment center

Name of recruitment center

Ahvaz Jundishapur University of Medical Sciences

Full name of responsible person

Anahita Borjian

Street address

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Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Jundishapur University of Medical Sciences

Full name of responsible person

Ahmadreza Mohtadi

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Anesthesiology department, Imam khomeyni hospital

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Grant name

Grant code / Reference number

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

Yes

Title of funding source

Jundishapur University of Medical Sciences

Proportion provided by this source

100

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

Person responsible for general inquiries**Contact****Name of organization / entity**

Jundishapur University of Medical Sciences

Full name of responsible person

Ahmadreza Mohtadi

Position

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Sharing plan**Deidentified Individual Participant Data Set (IPD)**

empty

Study Protocol

empty

Statistical Analysis Plan

empty

Informed Consent Form

empty

Clinical Study Report

empty

Analytic Code

empty

Data Dictionary

empty