

# 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

Salman vojdati

###### Name of organization / entity

Fasa University Of Medical Sceinces

###### Country

Iran (Islamic Republic of)

###### Phone

+98 939 735 6589

##### Email address

vojdati.s@ajums.ac.ir

##### 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

##### City

Ahvaz

## Sponsors / Funding sources

### 1

#### Sponsor

##### Name of organization / entity

Jundishapur University of Medical Sciences

##### Full name of responsible person

Ahmadreza Mohtadi

##### Street address

Anesthesiology department, Imam khomeyni hospital

##### City

Ahvaz

#### 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**

Assistant professor

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**Full name of responsible person**

Salman Vojdani

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**Full name of responsible person**

Anahita Borjian

**Position**

Resident of anesthesiology

**Other areas of specialty/work****Street address**

Imam Khomeini hospital

**City**

Ahvaz

**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*