

# Clinical Trial Protocol

## Iranian Registry of Clinical Trials

10 Jun 2026

### Effect of tranexamic acid on deep vein thrombosis and thromboembolism after surgery of femur fractures

#### Protocol summary

##### Study aim

Effect of tranexamic acid on deep vein thrombosis and thromboembolism after surgery of femur fractures

##### Design

Randomized Clinical trial with control group, parallel group

##### Settings and conduct

In this clinical trial, all patients who undergo open surgery and plaque surgery in Shahid Beheshti Hospital with Femur bone fractures diagnosis include the study.

##### Participants/Inclusion and exclusion criteria

Patient with femoral fracture that operated with open reduction and internal fixation. Anemia, Renal disease, History of ischemia, Myocardial, Hypertension, History of cerebral ischemia, History of thromboembolism.

##### Intervention groups

One group received 10 mg / kg of Tranexamic acid before the onset of surgery and 10 ml of normal saline was injected to another group.

##### Main outcome variables

Blood volume lost, The amount of blood you receive, Deep vein thrombosis and thromboembolism

#### General information

##### Reason for update

##### Acronym

##### IRCT registration information

IRCT registration number: **IRCT20180422039382N4**

Registration date: **2021-03-10, 1399/12/20**

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

Last update: **2021-03-10, 1399/12/20**

Update count: **0**

##### Registration date

2021-03-10, 1399/12/20

##### Registrant information

##### Name

Rahmatollah Jokar

##### Name of organization / entity

##### Country

Iran (Islamic Republic of)

##### Phone

+98 11 3219 9592

##### Email address

r.jokar@mubabol.ac.ir

##### Recruitment status

**Recruitment complete**

##### Funding source

##### Expected recruitment start date

2020-12-13, 1399/09/23

##### Expected recruitment end date

2021-12-14, 1400/09/23

##### Actual recruitment start date

empty

##### Actual recruitment end date

empty

##### Trial completion date

empty

##### Scientific title

Effect of tranexamic acid on deep vein thrombosis and thromboembolism after surgery of femur fractures

##### Public title

Effect of tranexamic acid on bleeding

##### Purpose

Prevention

##### Inclusion/Exclusion criteria

##### Inclusion criteria:

Patient with femoral fracture that operated with open reduction and internal fixation

##### Exclusion criteria:

Anemia Renal disease History of myocardial ischemia Hypertension History of cerebral ischemia History of thromboembolism

##### Age

No age limit

**Gender**

Both

**Phase**

3

**Groups that have been masked**

No information

**Sample size**

Target sample size: 90

**Randomization (investigator's opinion)**

Randomized

**Randomization description**

Samples will be divided into two groups of Control and intervention using Permuted Block Randomization. Number will be selected for allocation concealment by one of the colleagues and by another, that assignment chain is chosen.

**Blinding (investigator's opinion)**

Not blinded

**Blinding description**

**Placebo**

Used

**Assignment**

Parallel

**Other design features**

**Secondary Ids**

empty

**Ethics committees**

1

**Ethics committee**

**Name of ethics committee**

Ethics committee of Babol University of Medical Sciences

**Street address**

Babol University of Medical Sciences, Ganjafrooz Street, Babol, Mazandaran, Iran

**City**

Babol

**Province**

Mazandaran

**Postal code**

4716681451

**Approval date**

2020-11-23, 1399/09/03

**Ethics committee reference number**

IR.MUBABOL.REC.1399.410

**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 6hours after surgery

**Method of measurement**

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

**Secondary outcomes**

1

**Description**

Number of received packed cells

**Timepoint**

During surgery till 6 hours after surgery

**Method of measurement**

Number of packed cell

2

**Description**

Deep vein thrombosis and thromboembolism

**Timepoint**

During surgery till 6 hours after surgery

**Method of measurement**

Color Echo Doppler

**Intervention groups**

1

**Description**

Intervention group: Injection of 10 mg/kg intravenous tranexamic 5 min before skin incision in intervention group.

**Category**

Treatment - Drugs

2

**Description**

Control group: Injection of 10 mg/kg intravenous normal sailine 5 min before skin incision in control group.

**Category**

Treatment - Drugs

**Recruitment centers**

1

**Recruitment center**

**Name of recruitment center**

Babol Shahid Beheshti Hospital

**Full name of responsible person**

Dr. Rahmatollah Jokar

**Street address**

Babol University of Medical Sciences; Ganjafrooz  
Street; Babol; Iran

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+98 11 3225 6285

**Email**

Dr.jokar1@gmail.com

**Web page address**

<http://www.mubabol.ac.ir/>

## Sponsors / Funding sources

### 1

**Sponsor**

**Name of organization / entity**

Babol University of Medical Sciences

**Full name of responsible person**

Dr. Reza Ghadimi

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rezaghadimi@yahoo.com

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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**

Babol 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**

Babol University of Medical Sciences

**Full name of responsible person**

Hassan Aghabararzade omran

**Position**

Medical student

**Latest degree**

A Level or less

**Other areas of specialty/work**

General Practitioner

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## Person responsible for scientific inquiries

**Contact**

**Name of organization / entity**

Babol University of Medical Sciences

**Full name of responsible person**

Dr. Rahmatollah Jokar

**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**

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

No - There is not a plan to make this available

**Justification/reason for indecision/not sharing IPD**

-

**Study Protocol**

No - There is not a plan to make this available

**Statistical Analysis Plan**

No - There is not a plan to make this available

**Informed Consent Form**

No - There is not a plan to make this available

**Clinical Study Report**

No - There is not a plan to make this available

**Analytic Code**

No - There is not a plan to make this available

**Data Dictionary**

No - There is not a plan to make this available