

# Clinical Trial Protocol

## Iranian Registry of Clinical Trials

12 Jun 2026

### Effect of Tranexamic acid to reduce bleeding during surgery on fracture of femoral shaft aged in 20-50 year

#### Protocol summary

##### Summary

This study is a randomized clinical trial. The objective is to reduce bleeding during surgery on fracture of the femoral shaft. Inclusion criteria: lateral fractures of the femoral shaft, without any comminuted; no evidence of Ischemic heart disease or history of any treatment of heart disease before the operation; anticoagulant medications were not taken before surgery; they didn't have any evidence of brain trauma or history of stay in ICU caused by brain disease; also there weren't evidence of ischemic or hemorrhagic stroke including SAH (subarachnoid hemorrhage) of disease. Exclusion criterion: surgery takes time more than 90 minutes. In this study, population candidate for surgery Intramedullary nailing of femoral shaft fractures in age 20-50 years old. Patients' hemoglobin, Four hours before surgery was equal or more than 10 g/dl, and divided to two groups, one of them receive the medicine and the other one is control group that receive placebo. Each group consisted of 46 patients. Tranexamic acid group receiving 15 mg/kg drug and the other group receiving placebo (normal saline), an equal volume, within 10 minutes after induction of anesthesia and before skin incision infusion. Based on a formula called Chi-Square Test, bleeding during and after surgery in both groups that are receiving drug Tranexamic acid and placebo can be identified and compared.

#### General information

##### Acronym

##### IRCT registration information

IRCT registration number: **IRCT201104256280N1**  
Registration date: **2014-04-30, 1393/02/10**  
Registration timing: **prospective**

Last update:

Update count: **0**

##### Registration date

2014-04-30, 1393/02/10

##### Registrant information

###### Name

Mohammad Haghghi

###### Name of organization / entity

Guilan University of Medical Sciences

###### Country

Iran (Islamic Republic of)

###### Phone

+98 13 3211 1319

###### Email address

mohaghghi@gums.ac.ir

##### Recruitment status

**Recruitment complete**

##### Funding source

Guilan University of Medical Sciences

##### Expected recruitment start date

2014-07-16, 1393/04/25

##### Expected recruitment end date

2014-09-16, 1393/06/25

##### Actual recruitment start date

empty

##### Actual recruitment end date

empty

##### Trial completion date

empty

##### Scientific title

Effect of Tranexamic acid to reduce bleeding during surgery on fracture of femoral shaft aged in 20-50 year

##### Public title

Effect of Tranexamic acid reduces bleeding during surgery

##### Purpose

Prevention

##### Inclusion/Exclusion criteria

Inclusion criteria: lateral fractures of the femoral shaft

without any comminuted; no evidence of Ischemic, Heart disease or history of any treatment of Heart disease before the operation; anticoagulant medications were not taken before surgery; they didn't have any evidence of brain trauma or history of stay in intensive care unit (ICU) caused by brain disease, also there weren't evidence of Ischemic or hemorrhagic stroke including (SAH) subarachnoid hemorrhage of disease. Exclusion criterion: surgery takes time more than 90 minutes.

#### Age

From **20 years** old to **50 years** old

#### Gender

Both

#### Phase

2-3

#### Groups that have been masked

*No information*

#### Sample size

Target sample size: **80**

#### 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

Ethics Committee of Guilan University of Medical Sciences

##### Street address

Shahid Beheshti freeway

##### City

Rasht

##### Postal code

4193893345

#### Approval date

2013-12-07, 1392/09/16

#### Ethics committee reference number

1920341307

## Health conditions studied

### 1

#### Description of health condition studied

Femur fractures

#### ICD-10 code

S72.8

#### ICD-10 code description

Fractures of other parts of femur

## Primary outcomes

### 1

#### Description

Hemoglobin

#### Timepoint

Four hours before and after surgery up to 24 hours

#### Method of measurement

g/dl, Cell counter Sysmex KX-21

## Secondary outcomes

empty

## Intervention groups

### 1

#### Description

Interval 1 )Tranexamic acid 15 mg kg infusion for 10 minutes

#### Category

Treatment - Drugs

### 2

#### Description

Intervention 2) saline for 10 minutes

#### Category

Placebo

## Recruitment centers

### 1

#### Recruitment center

##### Name of recruitment center

Poursina hospital

##### Full name of responsible person

Mohammad Haghighi

##### Street address

Parastar Street

##### City

Rasht

## Sponsors / Funding sources

### 1

#### Sponsor

##### Name of organization / entity

Vice chancellor of Guilan University of Medical Sciences

##### Full name of responsible person

Abtin Heidarzadeh

##### Street address

Shahid beheshti Highway

**City**  
Rasht

**Grant name**  
**Grant code / Reference number**  
**Is the source of funding the same sponsor organization/entity?**  
Yes

**Title of funding source**  
Vice chancellor of Guilan 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**  
Guilan University of Medical Sciences

**Full name of responsible person**  
Mohammad Haghghi

**Position**  
Anesthesiologist/Associated Professor

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

**City**  
Rasht

**Postal code**  
4193833697

**Phone**  
+98 13 1321 0424

**Fax**  
+98 13 1324 5132

**Email**  
mohaghighi@gums.ac.ir; arcguilan1392@gmail.com

**Web page address**  
www.gums.ac.ir

## Person responsible for scientific inquiries

### Contact

**Name of organization / entity**  
Guilan University of Medical Sciences

**Full name of responsible person**  
Mohammad Haghghi

**Position**  
Associated Professor

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

**City**  
Rasht

**Postal code**  
4193833697

**Phone**  
+98 13 1321 0434

**Fax**  
+98 13 1324 5140

**Email**  
mohaghighi@gums.ac.ir; arcguilan1392@gmail.com

**Web page address**  
www.gums.ac.ir

## Person responsible for updating data

### Contact

**Name of organization / entity**  
Guilan University of Medical Sciences

**Full name of responsible person**  
Mohammad Haghghi

**Position**  
Anesthesiologist/Associated Professor

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

**City**  
Rasht

**Postal code**  
4193713194

**Phone**  
+98 13 1322 3970

**Fax**  
+98 13 1323 9842

**Email**  
mohaghighi@gums.ac.ir; arcguilan1392@gmail.com

**Web page address**  
www.gums.ac.ir

## 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*