

Clinical Trial Protocol

Iranian Registry of Clinical Trials

11 Jun 2026

Effect of intraoperative infusion of Tranexamic acid on blood loss volume during Femoral Fracture Surgery: A double-blinded clinical trial

Protocol summary

2017-06-27, 1396/04/06

Summary

In current prospective randomized double-blinded clinical trial, 60 patients, candidate for femoral fracture surgery with conture, with grade I or II of American society of anesthesiology (ASA), will be evaluated. Patients with hypersensitivity to tranexamic acid, coagulopathies and pregnancy will be excluded. All patients will undergo routine heparin administration, a day before surgery and required laboratory tests including coagulation factors and complete blood count will be collected. Anesthesia will be inducted using propofol, fentanyl, midazolam and atracurium. Patients randomly will be assigned to study groups via RAS software. In study group, 10 mg/kg tranexamic acid will be administered during 15 minutes prior to incision, and will be infused during surgery with dosage of 1 mg/kg/hr till end of the surgery. In control group, patients will receive normal saline serum as placebo in same volume of tranexamic acid during surgery. Maximum allowable blood loss formula will be used to evaluate intraoperative bleeding. Whereas, Intraoperative blood loss will be estimated by blinded anesthesiologist, using blood collected in suction reservoir and blood smeared gausses. During surgery and postoperatively, variables such as intraoperative bleeding, postoperative bleeding and blood transfusion during and after surgery will be assessed and recorded.

Registrant information

Name

Masoud Parish

Name of organization / entity

Tabriz University of Medical Sciences

Country

Iran (Islamic Republic of)

Phone

+98 41 3385 5842

Email address

parishm@tbzmed.ac.ir

Recruitment status

Recruitment complete

Funding source

Vice Chancellor for Research, Tabriz University of Medical Sciences

Expected recruitment start date

2017-05-05, 1396/02/15

Expected recruitment end date

2018-04-04, 1397/01/15

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Effect of intraoperative infusion of Tranexamic acid on blood loss volume during Femoral Fracture Surgery: A double-blinded clinical trial

Public title

Controlling femoral fracture surgery bleeding by tranexamic acid

Purpose

Treatment

Inclusion/Exclusion criteria

General information

Acronym

IRCT registration information

IRCT registration number: **IRCT2017050126328N3**

Registration date: **2017-06-27, 1396/04/06**

Registration timing: **registered_while_recruiting**

Last update:

Update count: **0**

Registration date

Inclusion criteria: patients candidate for femoral fracture surgery using conture; Class I or II according to ASA classification; aged more than 18 years old. Exclusion criteria: hypersensitivity to tranexamic acid; anemia (hemoglobin lower than 8 gram per 100 milliliter); avoidance from blood transfusion; history of anticoagulant consumption; history of coagulopathies; history of thromboembolism; history of cerebrovascular accidents; history of ischemic heart diseases; pregnancy; major cardiac or pulmonary diseases; hepatic or renal failure; history of epilepsy; history of re-surgery.

Age

From **18 years** old to **60 years** old

Gender

Both

Phase

2-3

Groups that have been masked

No information

Sample size

Target sample size: **60**

Randomization (investigator's opinion)

Randomized

Randomization description**Blinding (investigator's opinion)**

Double blinded

Blinding description**Placebo**

Used

Assignment

Parallel

Other design features

Randomization will be performed using table of random numbers via RAS software.

Secondary Ids

empty

Ethics committees**1****Ethics committee****Name of ethics committee**

Ethics committee of Tabriz University of Medical Sciences

Street address

Vice chancellor for research, Tabriz university of medical sceinces, Daneshgah square

City

Tabriz

Postal code**Approval date**

2017-04-10, 1396/01/21

Ethics committee reference number

IR.TBZMED.REC.1396.14

Health conditions studied**1****Description of health condition studied**

Femoral fracture intraoperative bleeding

ICD-10 code

S72

ICD-10 code description

Fracture of femur

Primary outcomes**1****Description**

blood loss volume in drain reservoir

Timepoint

during operation and till darin discharge

Method of measurement

maximum allowable blood loss formula

Secondary outcomes**1****Description**

volume of blood transfusion

Timepoint

during operation and during admission

Method of measurement

C.C.

Intervention groups**1****Description**

Intervention group: 15 minutes prior to incision, 10 mg/kg tranexamic acid will be administered and will be infused during surgery with dosage of 1 mg/kg/hr till end of the surgery.

Category

Treatment - Drugs

2**Description**

Control group: 15 minutes prior to incision, 10 mg/kg normal saline (placebo) will be administered and will be infused during surgery with dosage of 1 mg/kg/hr till end of the surgery.

Category

Placebo

Recruitment centers**1****Recruitment center****Name of recruitment center**

Shohada Hospital

Full name of responsible person

Dr. Masoud Parish

Street address

Shohada hospital, Golshahr street, Yaxchian, Tabriz,
Iran

City

Tabriz

Sponsors / Funding sources**1****Sponsor****Name of organization / entity**

Vice Chancellor for research of Tabriz University of
Medical Sciences

Full name of responsible person

Alireza Ostadrahimi

Street address

Vice chancellor for research, Tabriz University of
medical sciences, Daneshgah square

City

Tabriz

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

Yes

Title of funding source

Vice Chancellor for research of Tabriz 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**

Tabriz University of Medical Sciences

Full name of responsible person

Dr. Masoud Parish

Position

Associate Professor, Specialist in Anesthesiology

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

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Web page address**Person responsible for updating data****Contact****Name of organization / entity**

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Web page address**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