

Clinical Trial Protocol

Iranian Registry of Clinical Trials

01 Aug 2026

Comparison of femoral shaft fracture bleeding in the two methods of Tranexamic acid and controled hypotension

Protocol summary

Summary

The study aims: to reduce bleeding in major surgery. It is a blind study. Study of population: 60 orthopedic patients who need to have this surgery and are elective . Inclusion criteria for femoral shaft fractures are first time, non-emergency, aged 60-18 years and exclusion criteria are prohibition tranexamic acid and hypotension. In the first group of controlled hypotension using nitroglycerin during anesthesia and mean arterial pressure of 60 mmHg and 90-80 mmHg for systolic pressure is brought and in the second group that are normotensive, half hour before and after the anesthetic tranexamic acid is injected and Systolic arterial blood pressure is maintained in the range 130-120 and outside of this measures the medical therapy is performed and the patient is excluded of this study. All the patients are under general anesthesia.

General information

Acronym

IRCT registration information

IRCT registration number: **IRCT201111198131N1**

Registration date: **2012-02-27, 1390/12/08**

Registration timing: **retrospective**

Last update:

Update count: **0**

Registration date

2012-02-27, 1390/12/08

Registrant information

Name

Majid Abdaviazar Sharabiani

Name of organization / entity

Tehran University of Medical Sciences

Country

Iran (Islamic Republic of)

Phone

+98 21 7704 2205

Email address

abdaviazarmajid@yahoo.com

Recruitment status

Recruitment complete

Funding source

Vice-chancellor for reseach, Tehran University of Medical Sciences

Expected recruitment start date

2010-03-21, 1389/01/01

Expected recruitment end date

2011-10-22, 1390/07/30

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Comparison of femoral shaft fracture bleeding in the two methods of Tranexamic acid and controled hypotension

Public title

Tranexamic acid in reducing bleeding in the femoral shaft fracture surgery

Purpose

Treatment

Inclusion/Exclusion criteria

Inclusion criteria: femoral shaft fracture; the first time; non-emergency; age 60-18 years; Normotensive being; tourniquet is not used; the amount of Hgb in the range of 12-10; following a period of 3 hours. Exclusion criteria: prohibition hypotension (eg, cardiovascular disease); previous use of anticoagulants; unexpected factors that complicate or prolong the surgery; to be with multiple trauma; hypertensive patients; reintroduction; diseases that cause clotting disorders; including banning the use of tranexamic acid.

Age

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

Single blinded

Blinding description**Placebo**

Not used

Assignment

Parallel

Other design features**Secondary Ids**

empty

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

Tehran University of Medical Sciences

Street address

Pursina street, 16 Azar street

City

Tehran

Postal code**Approval date**

2010-04-13, 1389/01/24

Ethics committee reference number

42112

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

Fracture of shaft of femur

ICD-10 code

S72.3

ICD-10 code description

Fracture of shaft of femur

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

The amount of bleeding

Timepoint

during anesthesia

Method of measurement

Counting blood gases, the suction, and operation field

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

Hypotension

Timepoint

during anesthesia

Method of measurement

by NIBP

2**Description**

arrhythmia

Timepoint

during anesthesia

Method of measurement

by monitoring of ECG

3**Description**

sever bleeding

Timepoint

during anesthesia

Method of measurement

The number of blood gas , Surgery field, suction

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

tranexamic acid injection 500 mg Two Time

Category

Treatment - Drugs

2**Description**

TNG injection 5 Mic per min

Category

Treatment - Drugs

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

Rasul Akram hospital

Full name of responsible person**Street address****City**

Tehran

Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Tehran University of Medical Sciences

Full name of responsible person

Vice chancellor for research, Dr Akbar Fotuhi

Street address

Central organization of Tehran University of Medical Sciences, Gods street, Keshavarz street

City

Tehran

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

Yes

Title of funding source

Tehran 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**

Tehran University of Medical Sciences

Full name of responsible person

Majid Abdaviazar Sharabiani

Position

Resident of anesthesia

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

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Person responsible for scientific inquiries

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Person responsible for updating data

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Fax**Email****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