

Clinical Trial Protocol

Iranian Registry of Clinical Trials

04 Aug 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 Haghighi

Name of organization / entity

Guilan University of Medical Sciences

Country

Iran (Islamic Republic of)

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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 I)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

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Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Vice chancellor of Guilan University of Medical Sciences

Full name of responsible person

Abtin Heidarzadeh

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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

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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