Clinical Trial Protocol
Iranian Registry of Clinical Trials

18 Sep 2026

Comparison of the tranexamic acid effect with the control group on bleeding in patients undergoing femoral shaft fracture surgery in Khatam al Anbiya hospital in Zahedan in 2016-2017

Protocol summary

Summary

This study is aimed to evaluate the effect of tranexamic acid on bleeding in femoral shaft fracture surgery. It is a single-blind, randomized clinical trial. After inclusion in the study, the participants will be randomly divided into venous tranexamic acid group and control group. Sample size is about 150 patients. Inclusion criterion is patients above the age of 18 who are going to undergo femoral shaft fracture surgery in Khatam al Anbiya Hospital in 2016-2017 and exclusion criteria are allergy to tranexamic acid, coagulant use 5 days before the surgery, hematuria and platelet count less than 150000. The interventions are as follows: in the tranexamic acid group, a bolus of 10 mg/kg of tranexamic acid will be given before the surgery and then venous injection of 1 mg/kg/h of the tranexamic acid until the end of the surgery. In the control group, we will act just like the tranexamic acid group except that instead of tranexamic acid, normal saline will be used. The primary outcome measure is the amount of blood loss during the femoral shaft fracture surgery.

General information

Acronym

IRCT registration information

IRCT registration number: **IRCT2016061328437N1**
Registration date: **2016-08-20, 1395/05/30**
Registration timing: **registered_while_recruiting**

Last update:
Update count: **0**

Registration date

2016-08-20, 1395/05/30

Registrant information

Name

Mostafa Hosseini Mofrad

Name of organization / entity

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Recruitment status

Recruitment complete

Funding source

Zahedan University of Medical Sciences

Expected recruitment start date

2016-03-20, 1395/01/01

Expected recruitment end date

2017-03-19, 1395/12/29

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Comparison of the tranexamic acid effect with the control group on bleeding in patients undergoing femoral shaft fracture surgery in Khatam al Anbiya hospital in Zahedan in 2016-2017

Public title

Tranexamic acid effect on bleeding in femoral fracture surgery

Purpose

Prevention

Inclusion/Exclusion criteria

Inclusion criterion: patients above the age of 18 who are going to undergo femoral shaft fracture surgery in

Khatam al Anbiya Hospital in 2016-2017 Exclusion criteria: allergy to tranexamic acid; coagulant use 5 days before the surgery; hematuria and platelet count of less than 150000

Age

From **18 years** old to **139 years** old

Gender

Both

Phase

2-3

Groups that have been masked

No information

Sample size

Target sample size: **150**

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

Ethics Commitee of Zahedan University of Medical Sciences

Street address

Zahedan University of Medical Sciences and Health Services campus, Khalije Fars Blv, Doctor Hesabi Sq, Zahedan

City

Zahedan

Postal code

Approval date

2016-03-19, 1394/12/29

Ethics committee reference number

ir.zaums.rec.1394.435

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

Amount of blood loss during femoral shaft fracture surgery

Timepoint

During the surgery, up to 48 hours after the surgery

Method of measurement

By counting the bloody guazes and measuring the suctioned blood during the surgery and also the drainage up to 48 hours after surgery

Secondary outcomes

empty

Intervention groups

1

Description

Tranexamic acid group: Injection of a bolus of 10 mg/kg of tranexamic acid before the surgery and then venous injection of 1 mg/kg/h of that till the end of the surgery

Category

Prevention

2

Description

Control group: Just like the tranexamic acid group except that instead of tranexamic acid, normal saline will be used

Category

Prevention

Recruitment centers

1

Recruitment center

Name of recruitment center

Khatam al Anbiya Hospital

Full name of responsible person

Mostafa Hosseini Mofrad

Street address

Khatam al Anbiya Hospital, Jame Jam Blv, Zahedan

City

Zahedan

Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Vice chancellor for research, Zahedan University of Medical Sciences

Full name of responsible person

Hoshang Rafighdoost

Street address
Vice chancellor for research, Zahedan University of Medical Sciences campus, Jannat Blv, Zahedan
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Zahedan
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, Zahedan 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

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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