

Clinical Trial Protocol

Iranian Registry of Clinical Trials

03 Aug 2026

Effect of Tranexamic Acid on Blood Loss and transfusion in Femoral Fixation Surgeries

Protocol summary

Study aim

Effect of Tranexamic Acid on Blood Loss and transfusion in Femoral Fixation Surgeries

Design

A clinical trial with a parallel control group, do not blind, randomized

Settings and conduct

In this clinical trial, 60ASA class I and II patients, aged 16-65 years old, who were candidates for femoral fixation surgery, were randomly divided into two groups receiving Tranexamic acid(TXA) and control. In the TXA group, 30 minutes before surgery, an intravenous dose of 15 mg/ kg of Tranexamic acid was administered, and the 2nd group(control) received the same volume(200ml) of normal saline. Blood Loss, need for blood transfusions, platelet count, hematocrit, coagulation tests, and hemoglobin levels before and after surgery were recorded and compared in both groups.

Participants/Inclusion and exclusion criteria

Inclusion criteria: Ages between 16 and 65 years old; ASA Class 1 and 2; Exclusion criteria: History of coagulopathy and bleeding disorders; Renal impairment; History of using antiplatelet and anticoagulant; Acute infection; A history of malignancy and ASA above 2 and thromboembolic events; Hemoglobin levels less than 10; Sensitivity to tranexamic acid

Intervention groups

Patients were divided into two groups, receiver tranexamic acid (TXA) and control.

Main outcome variables

Hemoglobin level; bleeding rate; blood transfusion rate

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20171030037093N18**

Registration date: **2019-09-14, 1398/06/23**

Registration timing: **prospective**

Last update: **2019-09-14, 1398/06/23**

Update count: **0**

Registration date

2019-09-14, 1398/06/23

Registrant information

Name

Sadra Ansaripour

Name of organization / entity

Shahrekord University of Medical Sciences

Country

Iran (Islamic Republic of)

Phone

+98 31 3650 3487

Email address

st_ansari.s@skums.ac.ir

Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2019-10-02, 1398/07/10

Expected recruitment end date

2020-01-30, 1398/11/10

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Effect of Tranexamic Acid on Blood Loss and transfusion in Femoral Fixation Surgeries

Public title

Effect of Tranexamic Acid on Blood Loss and transfusion

in Femoral Fixation Surgeries

Purpose

Treatment

Inclusion/Exclusion criteria

Inclusion criteria:

Ages between 16 and 65 years old ASA Class 1 and 2

Exclusion criteria:

History of coagulopathy and bleeding disorders Renal impairment History of using antiplatelet and anticoagulant Acute infection A history of malignancy and ASA above 2 and thromboembolic events Hemoglobin levels less than 10 Sensitivity to tranexamic acid

Age

From **16 years** old to **65 years** old

Gender

Both

Phase

2

Groups that have been masked

No information

Sample size

Target sample size: **60**

Randomization (investigator's opinion)

Randomized

Randomization description

Patients are divided into two groups randomly by software using simple randomization.

Blinding (investigator's opinion)

Not blinded

Blinding description

Placebo

Not used

Assignment

Parallel

Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee

Ethics committee of Hormozgan University of Medical Sciences

Street address

Deputy of research and technology, the Supreme Prophet's Hospital, Bandar Abbas

City

Bandar Abbas

Province

Hormozgan

Postal code

9791991551

Approval date

2015-10-07, 1394/07/15

Ethics committee reference number

HUMS.REC.1394.59

Health conditions studied

1

Description of health condition studied

Femoral Fixation Surgeries

ICD-10 code

ICD-10 code description

Primary outcomes

1

Description

Hemoglobin level

Timepoint

On the first day after surgery

Method of measurement

measurement

2

Description

bleeding rate

Timepoint

After surgery at 6, 12, 24 hours after surgery

Method of measurement

measurement

3

Description

blood transfusion rate

Timepoint

During surgery and within 24 hours after surgery

Method of measurement

measurement

Secondary outcomes

empty

Intervention groups

1

Description

Intervention group: The trans-oxamic acid-receiving group was injected intravenously 30 min before surgery with a 15 mg / kg dose of tranexamic acid.

Category

Treatment - Drugs

2

Description

Control group: In control group, only normal saline was injected with equal volume of 200ml for 20 minutes

Category

Treatment - Drugs

Recruitment centers

1

Recruitment center

Name of recruitment center

Shahid Mohammadi Hospital of Bandar Abbas

Full name of responsible person

Hashem Jarineshin

Street address

Boulevard of the Islamic Republic of Iran, Bandar Abbas, Shahid Mohammadi Hospital

City

Bandar Abbas

Province

Hormozgan

Postal code

9791991551

Phone

+98 76 3334 7000

Email

Anrc.hums@gmail.com

Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Bandare-abbas University of Medical Sciences

Full name of responsible person

Abdul Azim Nejati Zadeh

Street address

Deputy of research and technology, East Side, Bandar Abbas Hospital, Bandar Abbas

City

Bandar Abbas

Province

Hormozgan

Postal code

9791991551

Phone

+98 71 3333 5794

Email

azimnejate@yahoo.com

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

Yes

Title of funding source

Bandare-abbas University of Medical Sciences

Proportion provided by this source

100

Public or private sector

Public

Domestic or foreign origin

Domestic

Category of foreign source of funding

empty

Country of origin**Type of organization providing the funding**

Academic

Person responsible for general inquiries

Contact

Name of organization / entity

Iran University of Medical Sciences

Full name of responsible person

Hashem Jarineshin

Position

Associate Professor of Anesthesiology

Latest degree

Specialist

Other areas of specialty/work

Anesthesiology

Street address

Department of Anesthesiology, Shahid Mohammadi Hospital

City

Bandar Abbas

Province

Hormozgan

Postal code

9791991551

Phone

+98 917 361 3464

Email

shmh@hums.ac.ir

Person responsible for scientific inquiries

Contact

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Person responsible for updating data

Contact

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Sharing plan**Deidentified Individual Participant Data Set (IPD)**

Undecided - It is not yet known if there will be a plan to make this available

Study Protocol

Undecided - It is not yet known if there will be a plan to

make this available

Statistical Analysis Plan

Undecided - It is not yet known if there will be a plan to make this available

Informed Consent Form

No - There is not a plan to make this available

Clinical Study Report

Undecided - It is not yet known if there will be a plan to make this available

Analytic Code

Yes - There is a plan to make this available

Data Dictionary

Yes - There is a plan to make this available

Title and more details about the data/document

Information about the main outcome can be shared.

When the data will become available and for how long

Start the access period 4 months after publishing the results

To whom data/document is available

Researchers working in academia

Under which criteria data/document could be used

Use data to complete clinical trial studies

From where data/document is obtainable

Shahid mohammadi hospital

What processes are involved for a request to access data/document

After the investigation of researcher request and presentation of required documents will be accessible.

Comments