

Clinical Trial Protocol

Iranian Registry of Clinical Trials

12 Jul 2026

Evaluation of the effect of tranexamic acid on homeostasis after tibial osteotomy

Protocol summary

Study aim

Evaluation of the effect of tranexamic acid on homeostasis after tibial osteotomy

Design

This study is a randomized clinical trial (quadruple blocks) without blinding, which will be performed in parallel groups with the participation of 120 patients who will be divided into three equal groups.

Settings and conduct

This study will be performed without blinding and in Imam Reza Hospital of Tabriz with the participation of 120 patients candidate for tibial osteotomy; Patients will be divided into three equal groups; Topical tranexamic acid will be used for one group and intravenous tranexamic acid for another; Normal saline serum will be used as a placebo for the control group.

Participants/Inclusion and exclusion criteria

Inclusion criteria will include: osteoarthritis of the knee joint and a candidate for surgery, and exclusion criteria will also include: previous history of knee surgery, homeostasis disorders, use of blood thinners, history of venous thrombosis. Depth and pathology will be on the outside of the knee.

Intervention groups

This study is a randomized clinical trial without blinding which will be performed to evaluate the effect of tranexamic acid on homeostasis after tibial osteotomy in 120 patients referred to Imam Reza Hospital in Tabriz. Patients will be divided into three equal groups and one will use topical tranexamic acid and the other will use intravenous tranexamic acid; Normal saline serum will be used as a placebo for the control group.

Main outcome variables

Bleeding

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20190325043107N25**

Registration date: **2022-01-05, 1400/10/15**

Registration timing: **prospective**

Last update: **2022-01-05, 1400/10/15**

Update count: **0**

Registration date

2022-01-05, 1400/10/15

Registrant information

Name

Mehdi Khanbabayi Gol

Name of organization / entity

Country

Iran (Islamic Republic of)

Phone

+98 41 3334 7054

Email address

khanbabayimehdi69@gmail.com

Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2022-01-20, 1400/10/30

Expected recruitment end date

2022-03-21, 1401/01/01

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Evaluation of the effect of tranexamic acid on homeostasis after tibial osteotomy

Public title

Effect of tranexamic acid on homeostasis after tibial stereotomy

Purpose
Prevention

Inclusion/Exclusion criteria
Inclusion criteria:
Osteoarthritis of the knee joint Candidate for surgery
Exclusion criteria:
History of previous knee surgery Disorders of homeostasis system Taking blood thinners History of deep vein thrombosis Pathology in the outer part of the knee

Age
From **18 years** old to **75 years** old

Gender
Both

Phase
2-3

Groups that have been masked
No information

Sample size
Target sample size: **120**

Randomization (investigator's opinion)
Randomized

Randomization description
Patients were divided into four groups by quadruple block method; For this purpose, 4 sheets of paper were prepared and the letter A was written on two sheets and the letter B was written on the sheet; The sheets were then placed in a sealed container and each patient who came was given one of the sheets by the statistical consultant and the person was divided into two groups based on it.

Blinding (investigator's opinion)
Not 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 Tabriz University of Medical Sciences

Street address

Imam Reza Hospital, Azadi Ave

City

Tabriz

Province

East Azarbaijan

Postal code

5165665631

Approval date

2020-09-07, 1399/06/17

Ethics committee reference number

IR.TBZMED.REC.1399.607

Health conditions studied

1

Description of health condition studied

Bleeding

ICD-10 code

D59.6

ICD-10 code description

Hemoglobinuria due to hemolysis from other external causes

Primary outcomes

1

Description

Bleeding

Timepoint

Every six hours to 72 hours after surgery

Method of measurement

View blood storage drains

Secondary outcomes

empty

Intervention groups

1

Description

Intervention group(1): This group will be given 15 kg / mg tranexamic acid as an intravenous infusion over 20 minutes and then a full intravenous infusion at a dose of 1 mg / kg per hour until the end of surgery.

Category

Treatment - Drugs

2

Description

Intervention group(2): In this group, topical tranexamic acid will be injected. In this group, 500 mg of traxamic acid will be injected at the surgical site 15 minutes before the start of surgery.

Category

Treatment - Drugs

3

Description

Control group: Fifteen milliliters of normal saline will be given to this group as an intravenous infusion over 20 minutes, followed by a full intravenous infusion at a dose of one milliliter per hour until the end of surgery.

Category

Recruitment centers

1

Recruitment center

Name of recruitment center

Imam Reza Hospital

Full name of responsible person

Jafar Solei,anpour Mokhtarmanand

Street address

Imam Reza Hospital, Azadi Ave

City

Tabriz

Province

East Azarbaijan

Postal code

6165665631

Phone

+98 21 3335 5921

Email

mkhanbabayi@yahoo.com

Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Tabriz University of Medical Sciences

Full name of responsible person

Parviz Shahabi

Street address

Tabriz University of Medical Sciences, Azadi Ave

City

Tabriz

Province

East Azarbaijan

Postal code

5981764863

Phone

+98 41 3333 5986

Email

Mkhanbabayi@yahoo.com

Grant name

Grant code / Reference number

Is the source of funding the same sponsor organization/entity?

Yes

Title of funding source

Tabriz 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

Person responsible for general inquiries

Contact

Name of organization / entity

Tabriz University of Medical Sciences

Full name of responsible person

Jafar Soleimanpour Mokhtarmanand

Position

Associate professor

Latest degree

Specialist

Other areas of specialty/work

Orthopedics

Street address

Imam Reza Hospital, Azadi Ave

City

Tabriz

Province

East Azarbaijan

Postal code

5165665631

Phone

+98 41 3335 7310

Email

Mkhanbabayi@yahoo.com

Person responsible for scientific inquiries

Contact

Name of organization / entity

Tabriz University of Medical Sciences

Full name of responsible person

Gholamreza Khorrami

Position

Doctor

Latest degree

Specialist

Other areas of specialty/work

Orthopedics

Street address

Imam Reza Hospital, Azadi Ave

City

Tabriz

Province

East Azarbaijan

Postal code

5165665631

Phone

+98 41 3335 7310

Email

GH_khorami@yahoo.com

Person responsible for updating data

Contact

Name of organization / entity

Tabriz University of Medical Sciences

Full name of responsible person

Mehdi Khanbabayi Gol

Position

MSc in Nursing Education

Latest degree

Master

Other areas of specialty/work

Nursery

Street address

Imam Reza Hospital, Azadi Ave

City

Tabriz

Province

East Azarbaijan

Postal code

5981764863

Phone

+98 41 3334 7054

Fax**Email**

Khanbabayimehdi69@gmail.com

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

Undecided - It is not yet known if there will be 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

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

Data Dictionary

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