

Clinical Trial Protocol

Iranian Registry of Clinical Trials

12 Jul 2026

Comparison of intravenous injection of tranexamic acid before and at the end of surgery with no injection of the drug to control bleeding after total knee arthroplasty (TKA).

Protocol summary

Study aim

The aim of this study is comparison of the effect of tranexamic acid injection before and at the end of surgery with no injection of the drug to control of bleeding in patients under total knee arthroplasty.

Design

Clinical trial with control group, with parallel, not blinded, not randomized groups on 153 patients.

Settings and conduct

This study is a clinical trial which is performed in Shariati, Sina and Milad hospitals in Isfahan. 153 patients who are eligible for inclusion in the study are selected through convenience sampling and divided into three groups of 51. In group A: One hour before surgery, 2 ampoules of 500 mg tranexamic acid are injected intravenously, in group B: At the end of surgery, 2 ampoules of 500 mg tranexamic acid are injected intravenously and in group C: Tranexamic acid is not injected at all. The measure of bleeding is intra drain blood (24 hours after surgery). The data recorded in the questionnaire include: Study group (A, B and C), age, gender, history of blood coagulation problems, patients with underlying disease and its type, history of thrombolysis and bleeding rate.

Participants/Inclusion and exclusion criteria

Inclusion criteria: 1) need total knee arthroplasty
2) Patients compliance to participate in the study.
Exclusion criteria: 1) coagulopathy 2) history of thrombophlebitis 3) history of cardiovascular and brain disease 4) Pregnancy

Intervention groups

Group A: One hour before surgery, 2 ampoules of 500 mg tranexamic acid are injected intravenously, in group B: At the end of surgery, 2 ampoules of 500 mg tranexamic acid are injected intravenously and in group C: Tranexamic acid is not injected at all. The measure of bleeding is intra drain blood (24 hours after surgery).

Main outcome variables

Effect of tranexamic acid injection on bleeding amount after total knee arthroplasty: Effect of injection time on bleeding amount after total knee arthroplasty.

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20200526047574N1**

Registration date: **2020-06-17, 1399/03/28**

Registration timing: **registered_while_recruiting**

Last update: **2020-06-17, 1399/03/28**

Update count: **0**

Registration date

2020-06-17, 1399/03/28

Registrant information

Name

Behnam Haghpanah

Name of organization / entity

Country

Iran (Islamic Republic of)

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Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2020-06-07, 1399/03/18

Expected recruitment end date

2020-09-08, 1399/06/18

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Comparison of intravenous injection of tranexamic acid before and at the end of surgery with no injection of the drug to control bleeding after total knee arthroplasty (TKA).

Public title

Effect of Tranexamic acid in reducing the bleeding of knee replacement

Purpose

Treatment

Inclusion/Exclusion criteria**Inclusion criteria:**

1)Patients need total knee replacement 2)Patients have no coagulation problems 3)Patients have no underlying disease 4)Patients have no history of thrombophlebitis 5)Patients compliance to participate in the study

Exclusion criteria:

1)Patients have coagulation problem 2)Patients have history of thrombophlebitis 3)Patients have history of cardiovascular and brain disease 4)Patients non compliance to participate in the study 5)Pregnancy

Age

From **53 years** old to **84 years** old

Gender

Both

Phase

N/A

Groups that have been masked*No information***Sample size**Target sample size: **153****Randomization (investigator's opinion)**

Not randomized

Randomization description**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 Isfahan University of Medical Science

Street address

School of Medicine, Isfahan University, Azadi Square, Isfahan

City

Isfahan

Province

Isfahan

Postal code

8174673441

Approval date

2020-01-22, 1398/11/02

Ethics committee reference number

IR.IAU.NAJAFABAD.REC.1398.010

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

knee replacement

ICD-10 code

M17

ICD-10 code description

Osteoarthritis of knee

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

The amount of blood collected inside the drains after surgery

Timepoint

24 hours after surgery

Method of measurement

Measuring the amount of blood collected inside the drains in cm3 (cc).

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

Observation the size of knee hemarthrosis after surgery

Timepoint

48 hours after surgery

Method of measurement

Observation and examination

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

Intervention group 1: 2 ampoules of 500 mg tranexamic acid, intravenously, One dose, One hour before surgery

Category

Treatment - Drugs

2**Description**

Intervention group 2: 2 ampoules of 500 mg tranexamic acid, intravenously, One dose, at the end of surgery.

Category
Treatment - Drugs

3

Description
Control group: No injection of tranexamic acid

Category
Treatment - Drugs

Recruitment centers

1

Recruitment center

Name of recruitment center
Dr. Ali Shariati hospital

Full name of responsible person
Dr. Behnam Haghpanah (Orthopedic surgen)

Street address
Dr. Ali Shariati hospital, Shariati Street, Chaharbagh Bala Street, Isfahan

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2

Recruitment center

Name of recruitment center
Milad hospital

Full name of responsible person
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3

Recruitment center

Name of recruitment center
Sina hospital

Full name of responsible person
Dr. Behnam Haghpanah (Orthopedic surgen)

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Sponsors / Funding sources

1

Sponsor

Name of organization / entity
Dr. Ali Shariati Hospital/ Orthopedic ward

Full name of responsible person
Dr. Behnam Haghpanah (Orthopedic Surgen)

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Dr. Ali Shariati Hospital, Shariati Street, Chaharbagh Bala Street, Isfahan

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Grant name

Grant code / Reference number

Is the source of funding the same sponsor organization/entity?
No

Title of funding source
Islamic Azad University, Najafabad Branch, Isfahan

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
School of medicine/Islamic Azad University, Najafabad Branch

Full name of responsible person

Anis Salimi

Position

Medical Student

Latest degree

Medical doctor

Other areas of specialty/work

Others

Street address

Second Floor, No. 486, Alley.1, Saadat Ave., Molana Ave., Shahrak-e Vali Asr., Janbazan Ave., Simin Cross., Isfahan

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Person responsible for scientific inquiries

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Full name of responsible person

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Position

Orthopedics surgen/ Associate professor of medical school

Latest degree

Specialist

Other areas of specialty/work

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Person responsible for updating data

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Name of organization / entity

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Full name of responsible person

Anis Salimi

Position

Medical Student

Latest degree

Medical doctor

Other areas of specialty/work

Others

Street address

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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

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