Clinical Trial Protocol
Iranian Registry of Clinical Trials

16 Sep 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 eligibled 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 tranexamc 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)

Phone

+98 31 3220 2418

Email address

behnamhaghpanah@smd.iaun.ac.ir

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
Isfehan
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 hosptal

Full name of responsible person

Dr. Behnam Haghpanah (Orthopedic surgen)

Street address

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

City

Isfahan

Province

Isfehan

Postal code

8173745384

Phone

+98 31 3627 2001

Email

behnamhaghpanah42@gmail.com

2

Recruitment center

Name of recruitment center

Milad hospital

Full name of responsible person

Dr. Behnam Haghpanah (Orthopedic surgen)

Street address

Milad hospital, Shahid Bakhshi Street, Janbazan Street, Simin Cross, Isfahan

City

Isfahan

Province

Isfehan

Postal code

8179663467

Phone

+98 31 3777 4001

Email

behnamhaghpanah42@gmail.com

3

Recruitment center

Name of recruitment center

Sina hospital

Full name of responsible person

Dr. Behnam Haghpanah (Orthopedic surgen)

Street address

Sina Hospital, Ghasr Cross, Shams Abadi Street, Isfahan

City

Isfahan

Province

Isfehan

Postal code

8135613477

Phone

+98 31 3220 5025

Email

behnamhaghpanah42@gmail.com

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)

Street address

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

City

Isfahan

Province

Isfehan

Postal code

8173745384

Phone

+98 31 3627 2001

Email

behnamhaghpanah42@gmail.com

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
City
Isfahan
Province
Isfehan
Postal code
8174799916
Phone
+98 31 3777 3623
Email
anis.salimi2013@gmail.com

Person responsible for scientific inquiries

Contact
Name of organization / entity
Islamic Azad University, Najafabad Branch
Full name of responsible person
Behnam Haghpanah
Position
Orthopedics surgen/ Associate professor of medical school
Latest degree
Specialist
Other areas of specialty/work
Orthopedics
Street address
Third Floor, No. 10, Iran Tour Alley., East Abbasabad Ave.
City
Isfahan
Province
Isfehan
Postal code
8134617551
Phone
+98 31 3220 2418
Email
behnamhaghpanah42@gmail.com

Person responsible for updating data

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
City
Isfahan
Province
Isfehan
Postal code
8174799916
Phone
+98 31 3777 3623
Email
anis.salimi2013@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