

Clinical Trial Protocol

Iranian Registry of Clinical Trials

19 Sep 2026

Intra-articular versus Intravenous Tranexamic Acid in total knee arthroplasty patients in Imam Khomeini Hospital 2017-2018

Protocol summary

Study aim

Comparative study of intra-articular and intravenous tranexamic acid effects on lowering postoperative blood loss in TKA patients in Imam Khomeini Hospital with aspirin as a VTE prophylaxis and no use of closed suction drain.

Design

In this prospective randomized clinical trial, TKA patients randomly allocated to two equal groups with IA and IV TXA injection.

Settings and conduct

A prospective randomized clinical trial study ran in Imam Khomeini hospital from July 2017 to February 2018

Participants/Inclusion and exclusion criteria

TKA patients who were operated in Imam Khomeini Hospital from July 2017 to February 2018 without any history of cardiovascular, bleeding and thrombosis diseases.

Intervention groups

49 TKA patients were intravenously given 15 mg/kg dose of TXA and 49 patients intraarticularly received 15 mg/kg of TXA

Main outcome variables

Demographic information, pre-operative and post-operative hemoglobin values of the patients were used for assessing total perioperative blood loss by GOOD & NADLER formulae.

General information

Reason for update

Acronym

TXA

IRCT registration information

IRCT registration number: **IRCT20160809029286N3**

Registration date: **2019-02-02, 1397/11/13**

Registration timing: **retrospective**

Last update: **2019-02-02, 1397/11/13**

Update count: **0**

Registration date

2019-02-02, 1397/11/13

Registrant information

Name

Alireza Moharrami

Name of organization / entity

Country

Iran (Islamic Republic of)

Phone

+98 21 4401 7418

Email address

a-moharrami@student.tums.ac.ir

Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2017-07-23, 1396/05/01

Expected recruitment end date

2018-03-20, 1396/12/29

Actual recruitment start date

2017-07-23, 1396/05/01

Actual recruitment end date

2018-03-20, 1396/12/29

Trial completion date

2018-03-20, 1396/12/29

Scientific title

Intra-articular versus Intravenous Tranexamic Acid in total knee arthroplasty patients in Imam Khomeini Hospital 2017-2018

Public title

Intra-articular versus Intravenous Tranexamic Acid in total knee arthroplasty

Purpose

Prevention

Inclusion/Exclusion criteria

Inclusion criteria:
Total knee arthroplasty candidate patients Surgery in Imam Khomeini Hospital Not having a specific bleeding disorder Not having any co-morbidity Not having any cardiovascular diseases Accept the terms of participation in the study voluntarily

Exclusion criteria:
Cardiovascular diseases Any co-morbidity Any bleeding disorders Thromboembolie and stroke history Not voluntary Sensitivity to tranexamic acid Revision TKA

Age
No age limit

Gender
Both

Phase
3

Groups that have been masked

- Participant
- Care provider

Sample size
Target sample size: **98**
Actual sample size reached: **98**

Randomization (investigator's opinion)
Randomized

Randomization description
The TKA candidate Patients randomly allocated to IA and IV TXA groups as a blind randomized clinical trial

Blinding (investigator's opinion)
Double blinded

Blinding description
During the injection of tranexamic acid, the person who do the injection hadn't any information of study. Patients are not aware of the medication model of injection. Patients are divided into groups by random code designed by the researcher and identified with the patient ID at the time of analysis.

Placebo
Not used

Assignment
Parallel

Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee

Ethics committee of Tehran University of Medical Science

Street address

Imam Khomeini Hospital, End of Keshavarz blvd, Keshavarz Blvd, Tehran

City

Tehran

Province

Tehran

Postal code

1419733141

Approval date

2017-07-15, 1396/04/24

Ethics committee reference number

IR.TUMS.VCR.REC.1396.2879

Health conditions studied

1

Description of health condition studied

Blood Loss after Total Knee Arthroplasty

ICD-10 code

M17

ICD-10 code description

Osteoarthritis of knee

Primary outcomes

1

Description

Post-operative Hb to pre-operative Hb

Timepoint

Pre-operative, 24 hour post-operative, 48 hour post-operative, 72 hour post-operative

Method of measurement

With blood lab test and blood loss calculation with GOOD & NADLER formulae

Secondary outcomes

1

Description

Occurrence of vascular thrombosis, DVT, Stroke and embolism

Timepoint

At least two years Follow-up

Method of measurement

Physical exam and para-clinics

Intervention groups

1

Description

Intervention group: 15 mg/kg TXA intra-Articular injection post-operative

Category

Treatment - Drugs

2

Description

Control group: 5 mg/kg TXA intravenous injection

Category

Treatment - Drugs

Recruitment centers

1

Recruitment center

Name of recruitment center

Imam Khomeini Complex Hospital

Full name of responsible person

Dr Seyed Mohammad Javad Mortazavi

Street address

Imam Khomeini Hospital, End of Keshavarza Blvd,
Tehran, IRAN

City

Tehran

Province

Tehran

Postal code

1419733141

Phone

+98 21 6119 0000

Email

Imamhospital@tums.ac.ir

Web page address

Http://ikhc.tums.ac.ir/

Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Joint Reconstruction Research Center

Full name of responsible person

Dr Seyed Mohammad Javad Mortazavi

Street address

Orthopaedic Ward, Imam Khomeini Hospital, End of
Keshavarz Blvd, Tehran

City

Tehran

Province

Tehran

Postal code

1419733141

Phone

+98 21 6119 0000

Email

Imamhospital@tums.ac.ir

Web page address

Http://www.ikch.tums.ac.ir

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

Yes

Title of funding source

Joint Reconstruction Research Center

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**

Tehran University of Medical Sciences

Full name of responsible person

Alireza Moharrami

Position

Orthopaedic Resident

Latest degree

Medical doctor

Other areas of specialty/work

Orthopedics

Street address

Orthopaedic Ward, Imam Khomeini Hospital, End of
Keshavarz Blvd, Tehran , IRAN

City

Tehran

Province

Tehran

Postal code

1955743849

Phone

+98 21 6119 0000

Fax**Email**

a-moharrami@student.tums.ac.ir

Web page address

Person responsible for scientific inquiries

Contact**Name of organization / entity**

Tehran University of Medical Sciences

Full name of responsible person

Dr Seyed Mohammad Javad Mortazavi

Position

Hip and Knee surgeon

Latest degree

Subspecialist

Other areas of specialty/work

Orthopedics

Street address

Orthopaedic Ward, Imam Khomeini Hospital, End of
Keshavarz Blvd, Tehran

City

Tehran

Province

Tehran

Postal code

1419733141

Phone

+98 21 6653 1354

Fax**Email**

smjmort@yahoo.com

Web page address

Person responsible for updating data

Contact

Name of organization / entity

Tehran University of Medical Sciences

Full name of responsible person

Alireza Moharrami

Position

Orthopaedic Resident

Latest degree

Medical doctor

Other areas of specialty/work

Orthopedics

Street address

Orthopaedic Ward, Imam Khomeini Hospital, End of Keshavarz Blvd, Tehran, IRAN

City

Tehran

Province

Tehran

Postal code

1955743849

Phone

+98 21 6119 0000

Fax

Email

a-moharrami@student.tums.ac.ir

Web page address

Sharing plan

Deidentified Individual Participant Data Set (IPD)

Yes - There is a plan to make this available

Study Protocol

Yes - There is a plan to make this available

Statistical Analysis Plan

Yes - There is a plan to make this available

Informed Consent Form

Yes - There is a plan to make this available

Clinical Study Report

Yes - There is 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

In the end of study, All data Except Demographics will be published.

When the data will become available and for how long

June 2019

To whom data/document is available

Orthopaedic Surgeons

Under which criteria data/document could be used

There are no special conditions

From where data/document is obtainable

Anyone can request study data by sending an email to the plan executor (Alireza Moharrami).

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

Within 2 weeks will be answered.

Comments

-