

# Clinical Trial Protocol

## Iranian Registry of Clinical Trials

13 Jun 2026

### Intra-articular vs Intravenous vs combine IVIA Tranexamic Acid in total knee arthroplasty patients

#### Protocol summary

##### Study aim

Comparison the effect of intra-articular and intravenous and combine IA & IV tranexamic acid on lowering postoperative blood loss in TKA patients with aspirin as a VTE prophylaxis and no uses of close suction drain.

##### Design

In this prospective randomized clinical trial, TKA patients randomly allocated to three equal groups with IA, IV and combine IVIA TXA injection. The study was parallel and double blinded which the patients and assessor were blinded from the study. Randomization was performed by the permuted balanced blocks method for all the patients.

##### 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

Inclusion criteria: The patients who underwent TKA surgery in Imam Khomeini Hospital Exclusion Criteria: Any history of cardiovascular, Bleeding and thrombosis diseases. Revision TKA surgery

##### Intervention groups

49 TKA patients were intravenously (IV) given 15 mg/kg dose of TXA, 49 patients intraarticularly (IA) received 15 mg/kg of TXA and 49 patents received both IV and IA injection 15 mg/kg in each method

##### 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

##### IRCT registration information

IRCT registration number: **IRCT20160809029286N6**

Registration date: **2020-04-29, 1399/02/10**

Registration timing: **retrospective**

Last update: **2020-04-29, 1399/02/10**

Update count: **0**

##### Registration date

2020-04-29, 1399/02/10

##### 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

1917-07-23, 1296/05/01

##### Actual recruitment end date

2018-03-20, 1396/12/29

##### Trial completion date

2018-03-20, 1396/12/29

##### Scientific title

Intra-articular vs Intravenous vs combine IVIA  
Tranexamic Acid in total knee arthroplasty patients

##### Public title

Intra-articular vs Intravenous vs combine IVIA  
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
- Investigator
- Outcome assessor

**Sample size**  
Target sample size: **147**  
Actual sample size reached: **147**

**Randomization (investigator's opinion)**  
Randomized

**Randomization description**  
For randomization, the permuted balanced blocks method was used. In this method, six balanced blocks (1 to 6) were defined regarding the three interventions of the study (A, B, C) including BAC, ACB, ABC, CAB, BCA and CBA . The patients were divided into 49 groups of three patients. The patients' numbers were inserted from 1 to 147 in a column using MS Excel software. In another column, the group of each patient was inserted, for example: patients 1 to 3 as group 1, patients 4 to 6 as group 2, ..., patients 144 to 147 as group 49. In another Excel sheet, the groups were inserted from 1 to 49, and the blocks were inserted across each group from 1 to 6 in order till the end. In the next column, non-repeated random numbers were inserted using the "RANDL()" command. Subsequently, the order of the blocks was randomly changed. According to the block assigned with each group, the intervention regarding each patient was determined. For example, if group 1 is assigned with "CAB", the interventions were as follows: Patient 1, C; Patient 2, A; Patient 3, B.

**Blinding (investigator's opinion)**  
Double blinded

**Blinding description**  
During the injection of tranexamic acid, the person who does the injection hadn't any information about the 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**  
mam 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**

Intervention group: 15 mg/kg TXA intravenous injection before the surgery and performing tourniquet

##### **Category**

Treatment - Drugs

#### **3**

##### **Description**

Intervention group: TXA was injected in combination of postoperative intra-Articular and preoperative intravenous methods and 15 mg/kg for each method

##### **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

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###### **Phone**

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###### **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

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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**

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

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## Person responsible for scientific inquiries

### Contact

**Name of organization / entity**

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**Full name of responsible person**

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**Position**

Hip and Knee surgeon

**Latest degree**

Subspecialist

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## Person responsible for updating data

### Contact

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**Full name of responsible person**

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**Position**

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**Latest degree**

Medical doctor

**Other areas of specialty/work**

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**Province**

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## 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**

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

**When the data will become available and for how long**

July 2020

**To whom data/document is available**

Orthopedic 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**

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