Clinical Trial Protocol
Iranian Registry of Clinical Trials

18 Sep 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

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Iran (Islamic Republic of)

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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 sheath, 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

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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

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Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Joint Reconstruction Research Center

Full name of responsible person

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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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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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