Clinical Trial Protocol
Iranian Registry of Clinical Trials

17 Sep 2026

The effect of using tourniquet and IV tranexamic acid on clinical outcomes and blood loss in unilateral Total Knee Arthroplasty (TKA) surgery: a randomized clinical trial

Protocol summary

Study aim
Investigating the effect of tourniquet and intravenous tranexamic acid on clinical outcomes and bleeding rate in unilateral total knee arthroplasty surgery.

Design
Clinical trial with a control group, with parallel groups, double-blind, randomized, phase 2 on 168 patients. Block method is used for randomization.

Settings and conduct
A clinical trial with a control group, in the Orthopedic Research Center of Ghaem Mashhad Hospital and double-blind (patient and analyzer)

Participants/Inclusion and exclusion criteria
Patients referring to the knee specialist clinic of Ghaem Hospital in Mashhad city with indications for total knee arthroplasty between 1401 and 1402 were included in the study. Patients are electively subjected to TKA surgery in Ghaem Hospital by a knee surgeon.

Intervention groups
Intervention 1: 42 patients undergoing elective total knee arthroplasty (TKA) with indications for the surgery at Qaem Hospital by a knee subspecialist surgeon receive 1000 milligrams of intravenous tranexamic acid (TXA) 30 minutes before incision and an additional 1000 milligrams of intravenous tranexamic acid at the time of wound closure, alongside the use of tourniquet during the operation. Intervention 2: 42 patients undergoing elective total knee arthroplasty (TKA) with indications for the surgery at Qaem Hospital by a knee subspecialist surgeon do not receive TXA injection and tourniquet is used during the operation. Intervention 3: 42 patients undergoing elective total knee arthroplasty (TKA) with indications for the surgery at Qaem Hospital by a knee subspecialist surgeon receive 1000 milligrams of intravenous tranexamic acid (TXA) 30 minutes before incision and an additional 1000 milligrams of intravenous tranexamic acid at the time of wound closure, without the use of tourniquet during the operation.

Main outcome variables
Bleeding volume, clinical outcomes (pain, joint function)

General information

Reason for update

Acronym

IRCT registration information
IRCT registration number: **IRCT20221228056952N1**
Registration date: **2023-12-30, 1402/10/09**
Registration timing: **registered_while_recruiting**

Last update: **2023-12-30, 1402/10/09**
Update count: **0**

Registration date
2023-12-30, 1402/10/09

Registrant information

Name
Mahla Daliri Beirak Olia

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
2023-12-29, 1402/10/08

Expected recruitment end date
2024-04-27, 1403/02/08

Actual recruitment start date
empty

Actual recruitment end date
empty
Trial completion date
empty

Scientific title
The effect of using tourniquet and IV tranexamic acid on clinical outcomes and blood loss in unilateral Total Knee Arthroplasty (TKA) surgery: a randomized clinical trial

Public title
Using tourniquet and IV tranexamic acid in unilateral Total Knee Arthroplasty (TKA) surgery
Purpose
Treatment
Inclusion/Exclusion criteria
Inclusion criteria:
Patients who refer to Ghaem hospital knee orthopedic clinic Indicated for unilateral total knee arthroplasty (TKA) surgery
Exclusion criteria:
allergy to TXA Active thromboembolic disease Seizure disorder Prior cerebrovascular accident Cardiac stents or a history of thromboembolic disease Prior renal disorder (glomerular filtration rate < 30 ml/min/1.73m2)
Age
From **18 years** old to **60 years** old
Gender
Both

Phase
3
Groups that have been masked

- Outcome assessor
- Data analyser

Sample size
Target sample size: **168**
Randomization (investigator's opinion)
Randomized
Randomization description
The random assignment of eligible people to the study is done by a person who is independent from the research team and is not involved in the process of treatment, follow-up of participants, data collection and recording. In order to achieve an equal number of patients in the groups under study and the least amount of difference in the number of people participating in the groups, the allocation of people will be done by block randomization. Due to the fact that 4 groups will be examined and compared in this research, blocks of 4 were used. Based on this and according to the calculated sample size, 42 blocks of four were considered. After the eligible subjects were determined to enter the study and their informed consent in the study was ensured, they were randomly assigned to the groups under study (the group using intravenous TXA, the group using topical TXA in solution and control group) will be allocated. Randomization will be performed using a computerized random assignment sequence. The belonging of people/patients to the groups under study will be blind for the patient, doctor/interventionist, and the person evaluating the results, so that first 42 envelopes containing 4 cards with letter labels indicating the belonging of the patients to the groups under study, will be prepared and given inside opaque envelopes. These envelopes are placed by the secretary of the department, who are not involved in research and recording the outcomes under study. Data before and after the surgical process will be collected and recorded by researchers other than the surgeon.
Blinding (investigator's opinion)
Double blinded
Blinding description
The belonging of people/patients to the groups under study will be blind to the evaluators of outcomes and the biostatistician who analyzes the data. We will assign unique identifiers or codes to each participant that do not reveal their treatment allocation. These codes will be used in all documentation instead of identifiable information. The actual treatment allocation for each participant will be kept in sealed, opaque envelopes or stored in a secure, restricted-access database. Only specific personnel (e.g., an independent coordinator) will have access to these codes. Outcome evaluators will use forms that contain only the coded identifiers, ensuring no direct indication of treatment allocation is present in the data collection materials. Data collected by evaluators will be stored separately from any information that discloses treatment allocation. This separation will prevent unintentional unblinding during data handling. Data provided to the biostatistician for analysis will only include the coded identifiers and outcome data without any reference to treatment allocation. Results presented to the biostatistician for interpretation should maintain the blinding by using only the coded identifiers without any treatment-related information.
Placebo
Used
Assignment
Parallel
Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee
Name of ethics committee
The Ethics Committee for Research at the Faculty of Medicine, Mashhad University of Medical Sciences
Street address
Mashhad, Daneshgah street, Central Organization of Mashhad University of Medical Sciences, Ghoreishi Building.
City
Mashhad
Province
Razavi Khorasan
Postal code
9176699199
Approval date

2023-06-27, 1402/04/06

Ethics committee reference number

IR.MUMS.MEDICAL.REC.1402.190

Health conditions studied

1

Description of health condition studied

Knee osteoarthritis

ICD-10 code

M17.1

ICD-10 code description

Unilateral primary osteoarthritis of knee

2

Description of health condition studied

Unilateral total knee arthroplasty

ICD-10 code

ICD-10 code description

Primary outcomes

1

Description

Blood loss volume

Timepoint

After surgery

Method of measurement

Postoperatively, blood loss will be calculated on the basis of the validated Gross formula, which includes sex, height, and weight, as well as pre-operative and postoperative day 2 hematocrit values with correction for any volume of blood administered.

2

Description

Surgeon satisfaction with visualization during the procedure

Timepoint

After surgery

Method of measurement

Using a 10-point visualization scale, with 0 categorized as ‘‘poor’’ and 10 categorized as ‘‘good.’’ This will be completed by the operative surgeon at the end of the case.

3

Description

Clinical outcomes

Timepoint

2 and 6 months follow-up after surgery

Method of measurement

Pain score using Visual analogue scale (VAS), a 10-point visualization scale. Knee functional questionnaires of Oxford Knee Score, and WOMAC.

Secondary outcomes

empty

Intervention groups

1

Description

Intervention group 1: 1000 mg of intravenous tranexamic acid 30 minutes prior to the incision plus 1000 mg of intravenous tranexamic acid during wound closure. Using tourniquet during the procedure.

Category

Treatment - Surgery

2

Description

Control group: Without tranexamic acid injection and without tourniquet application

Category

Treatment - Surgery

3

Description

Intervention group 2: Without tranexamic acid injection and with tourniquet application

Category

Treatment - Surgery

4

Description

Intervention group 3: 1000 mg of intravenous tranexamic acid 30 minutes prior to the incision plus 1000 mg of intravenous tranexamic acid during wound closure. Without using tourniquet during the procedure.

Category

Treatment - Surgery

Recruitment centers

1

Recruitment center

Name of recruitment center

Ghaem hospital

Full name of responsible person

Dr. Mohammad-Hossein Ebrahimzadeh

Street address

Ahmadabad street, Ghaem hospital

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Postal code

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Phone

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Email

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2

Recruitment center

Name of recruitment center
Imam Hassan Hospital

Full name of responsible person
Dr. Reza Ganji

Street address
Arkan Road, Pardis campus, Imam Hassan Educational and Research Center

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Bojnord

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Sponsors / Funding sources

1

Sponsor

Name of organization / entity
Mashhad University of Medical Sciences

Full name of responsible person
Dr. Mohsen Tafaghodi

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Grant name

Grant code / Reference number

Is the source of funding the same sponsor organization/entity?
Yes

Title of funding source
Mashhad University of Medical Sciences

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
Mashhad University of Medical Sciences

Full name of responsible person
Dr. Mohammad-Hossein Ebrahimzadeh

Position
Professor

Latest degree
Subspecialist

Other areas of specialty/work
Orthopedics

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Other areas of specialty/work
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Sharing plan

Deidentified Individual Participant Data Set (IPD)
No - There is not a plan to make this available
Justification/reason for indecision/not sharing IPD
Confidentiality
Study Protocol
Yes - There is a plan to make this available
Statistical Analysis Plan
No - There is not 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
No - There is not a plan to make this available
Data Dictionary
No - There is not a plan to make this available
Title and more details about the data/document
Clinical trial protocol publication Article publication
When the data will become available and for how long
Available immediately after results publication
To whom data/document is available
Orthopedics researchers
Under which criteria data/document could be used
Formal email with acceptable reason like meta-analysis on data
From where data/document is obtainable
Dr. Mohammad-Hossein Ebrahimzadeh-Orthopedics Research Center Director
What processes are involved for a request to access data/document
Email to Ebrahimzadehmh@mums.a.ir
Comments