Clinical Trial Protocol
Iranian Registry of Clinical Trials

16 Sep 2026

Evaluating efficacy and safety of topical and intravenous tranexamicacid for reducing peri/postoperative blood loss in primary Total knee arthroplasty

Protocol summary

Study aim
Comparing the effectiveness of tranexamic acid in simultaneous intravenous and intra-articular administration compared to only intra-articular administration in controlling bleeding after knee joint replacement surgery.

Design
The clinical trial has two groups that are conducted in both interventions in the form of parallel groups, unbiased, randomized and has 1 overall phase.

Settings and conduct
The place of operation is Akhtar Hospital. How to do the work: Selection of patients in need of knee joint replacement referring to the specialized clinic of Akhtar Hospital

Participants/Inclusion and exclusion criteria
Entry: Patients referred to Akhtar Hospital clinic who suffered from severe knee arthritis and their pain is not controlled by drug treatment and are candidates for knee joint replacement. Non-entry: patients who have contraindications for receiving tranexamic acid, such as a history of venous thrombosis

Intervention groups
This intervention includes two groups: the first group of knee joint replacement patients receive tranexamic acid simultaneously intravenously and intra-articularly. The second group of knee joint replacement patients receive tranexamic acid only intra-articularly.

Main outcome variables
Comparing the effectiveness of tranexamic acid in simultaneous intravenous and intra-articular administration compared to only intra-articular administration

General information

Reason for update

Acronym

IRCT registration information
IRCT registration number: **IRCT20220222054093N1**
Registration date: **2022-09-24, 1401/07/02**
Registration timing: **prospective**

Last update: **2022-09-24, 1401/07/02**
Update count: **0**

Registration date
2022-09-24, 1401/07/02

Registrant information

Name
Seyyed Morteza Kazemi

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
2022-10-09, 1401/07/17

Expected recruitment end date
2023-04-19, 1402/01/30

Actual recruitment start date
empty

Actual recruitment end date
empty

Trial completion date
empty

Scientific title
Evaluating efficacy and safety of topical and intravenous

tranexamicacid for reducing peri/postoperative blood loss in primary Total knee arthroplasty

Public title
Comparison of the effectiveness of tranexamic acid drug in simultaneous intravenous and joint administration compared to only joint administration in reducing bleeding after knee joint replacement surgery.

Purpose
Treatment

Inclusion/Exclusion criteria
Inclusion criteria:
Patients with severe knee osteoarthritis whose pain is not controlled by drug treatment and are candidates for joint replacement.
Exclusion criteria:
Patients who have contraindications to receive tranexamic acid

Age
No age limit

Gender
Both

Phase
3

Groups that have been masked

- Participant
- Care provider
- Investigator
- Outcome assessor
- Data analyser

Sample size
Target sample size: **60**
More than 1 sample in each individual
Number of samples in each individual: **1**
Hemoglobin level after the operation compared to before the operation to control the amount of bleeding

Randomization (investigator's opinion)
Randomized

Randomization description
Simple randomization, block.Patients who need knee joint replacement on the morning of the operation are randomly selected to receive tranexamic acid simultaneously intravenously and intra-articularly or only intra-articularly.

Blinding (investigator's opinion)
Double blinded

Blinding description
Participant: On the morning of the operation, we explain to the patient alternately, consecutively and randomly that we intend to use a method to reduce bleeding after the operation, but we do not know whether he is in the group receiving simultaneous venous and joint or only joint. does not have. The surgeon: He does not know about the selection of the patient who is part of the simultaneous intravenous and joint group or only the joint. The main researcher: He does not know about the selection of the patient who is part of the simultaneous intravenous and joint group or only the joint group. Doctors, nurses, physiotherapists, etc.: They don't know about the choice of the patient who is part of the simultaneous intravenous and joint receiving group or only joint.

Placebo
Not used

Assignment
Parallel

Other design features
It does not have unique characteristics

Secondary Ids

empty

Ethics committees

1

Ethics committee
Name of ethics committee
Organizational committee of ethics in biomedical research
Street address
3rd floor- Faculty of Medicine -- next to Taleghani Hospital- EvinShahid Chamran Highway-Tehran
City
tehran
Province
Tehran
Postal code
1985717434

Approval date
2022-08-14, 1401/05/23

Ethics committee reference number
IR.SBMU.RETECH.REC.1401.320

Health conditions studied

1

Description of health condition studied
Reduction of bleeding during knee replacement surgery among subjects receiving intravenous and intra-articular tranexamic acid and subjects receiving intra-articular only.

ICD-10 code
81.41

ICD-10 code description
total knee replacement

Primary outcomes

1

Description
Determination of efficacy and safety of intra-articular and intravenous TXA in primary TKA

Timepoint
The intravenous group receives 15 mg per kilogram of the patient's weight intravenously, 5 minutes before the tourniquet is inflated, and 5 minutes after the completion of the skin suture and before the opening of the tourniquet, the same intravenous dose is injected again. The local group receives only 15 mg of tranexamic acid

per kilogram of the patient's weight after the completion of the skin suture and 5 minutes before opening the tourniquet. The amount of hemoglobin after the operation is measured at intervals of 6 hours, 12 hours, 24 hours and 48 hours. In addition, the need for blood transfusion is also checked.

Method of measurement

Laboratory test

Secondary outcomes

empty

Intervention groups

1

Description

Intervention group: First group: patients who receive a single dose of tranexamic acid intravenously before the start of the operation, and at the end of the operation, a single dose is injected intra-articularly. The second group of patients who receive only one intra-articular dose of tranexamic acid at the end of the operation. This drug is Iranian and manufactured by Caspian Tamim.

Category

Treatment - Surgery

Recruitment centers

1

Recruitment center

Name of recruitment center

Akhtar hospital

Full name of responsible person

Seyed Morteza Kazemi

Street address

Akhtar Hospital, Sharifi Menesh St.,, Roman BridgeShariati St

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Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Shahid Beheshti University of Medical Sciences

Full name of responsible person

Vice President of Research and Technology

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Bone and Joint Research Center,Akhtar Hospital, Sharifi Menesh Street,, Rumi Bridge, Shariati Street

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boneresearch@sbmu.ac.ir

Grant name

Grant code / Reference number

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

No

Title of funding source

Bone, joint and related tissues 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

Shahid Beheshti University of Medical Sciences

Full name of responsible person

Dr seyed Mehdi Hoseini

Position

Associate professor

Latest degree

Specialist

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
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
Title and more details about the data/document
Still undecided - no release schedule yet
When the data will become available and for how long
Still undecided - no release schedule yet
To whom data/document is available
Still undecided - no release schedule yet
Under which criteria data/document could be used
Still undecided - no release schedule yet
From where data/document is obtainable
Still undecided - no release schedule yet
What processes are involved for a request to access data/document
Still undecided - no release schedule yet
Comments