

Clinical Trial Protocol

Iranian Registry of Clinical Trials

04 Jul 2026

Evaluating efficacy and safety of topical and intravenous tranexamic acid 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

Country

Iran (Islamic Republic of)

Phone

+98 21 2260 5090

Email address

morteza@sbmu.ac.ir

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

tranexamic acid 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

City

Tehran

Province

Tehran

Postal code

1964714953

Phone

+98 21 2200 1072

Email

kazemimort@gmail.com

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

Street address

Bone and Joint Research Center,Akhtar Hospital,

Sharifi Menesh Street,, Rumi Bridge, Shariati Street

City

tehran

Province

Tehran

Postal code

1964714953

Phone

+98 21 2260 5090

Email

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

Street address

Akhtar Hospital, Sharifi Menesh Street,, Rumi BridgeShariati Street

City

tehran

Province

Tehran

Postal code

1964714953

Phone

+98 21 2260 5090

Email

smhaa303@gmail.com

Person responsible for scientific inquiries**Contact****Name of organization / entity**

Shahid Beheshti University of Medical Sciences

Full name of responsible person

seyed mehdi hoseini

Position

Associate professor

Latest degree

Specialist

Other areas of specialty/work

Orthopedics

Street address

Akhtar Hospital, Sharifi Menesh Street,, Rumi
BridgeShariati Street

City

tehran

Province

Tehran

Postal code

1964714953

Phone

0098 21 2205090

Email

smhaa303@gmail.com

Person responsible for updating data

Contact

Name of organization / entity

Shahid Beheshti University of Medical Sciences

Full name of responsible person

seyed mehdi hoseini

Position

Associate professor

Latest degree

Specialist

Other areas of specialty/work

Orthopedics

Street address

Akhtar Hospital, Sharifi Menesh Street,, Rumi
BridgeShariati Street

City

Tehran

Province

Tehran

Postal code

1964714953

Phone

+98 21 2260 5090

Email

smhaa303@gmail.com

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