Clinical Trial Protocol
Iranian Registry of Clinical Trials

22 Nov 2026

Evaluation of the effects of Three Methods of Tranexamic Acid Administration on post operative blood loss following total knee arthroplasty compared with the control group

Protocol summary

Study aim
Determination of the effects of Three Methods of Tranexamic Acid Administration on post operative blood loss following total knee arthroplasty compared with the control group

Design
A randomized, double-blinded, controlled trial design of 200 patients

Settings and conduct
Between Sep 2019 and March 2020, patients who is scheduled to undergo a unilateral total knee arthroplasty in two educational hospitals of Kerman University of Medical Sciences will be enrolled in the study. Neither the patient nor the physician who assessed the results knew the patient's study group.

Participants/Inclusion and exclusion criteria
200 patients who scheduled to undergo a unilateral primary TKA were enrolled in the study who all gave their written informed consent for participation in the study. The exclusion criteria were the patients with cardiovascular diseases including myocardial infarction, atrial fibrillation and angina; Cerebrovascular diseases and history of thromboembolic disease, bleeding disorder, known allergy to tranexamic acid, and receiving the anti-coagulant drugs.

Intervention groups
Patients in group 1, received 10 mg/kg intravenous tranexamic acid in 100cc saline; immediately after the wound closure. In patients in group 2, knee joint with 3 g of tranexamic acid in 100 cc saline was washed before the closure of the wound for 5 minutes. In patients in group 3, immediately after the closure of the wound, 1.5 grams of tranexamic acid in 100cc saline will be injected into the knee joint through the drainage. Group 4 (control group) is not treated with tranexamic acid, and the drain is only clamped for one hour and then opened. In all groups, only one drain is inserted deeply into the knee joint, and clamped for an hour and then completely opened and released after 48 hours.

Main outcome variables
The amount of hemoglobin, post-operative total blood loss

General information

Reason for update

Acronym

IRCT registration information
IRCT registration number: **IRCT20160105025871N2**
Registration date: **2019-10-19, 1398/07/27**
Registration timing: **registered_while_recruiting**

Last update: **2019-10-19, 1398/07/27**
Update count: **0**

Registration date
2019-10-19, 1398/07/27

Registrant information

Name
Pardis Sasani

Name of organization / entity
Tehran University of Medical Sciences

Country
Iran (Islamic Republic of)

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+98 21 8855 0680

Email address
p_sasani@razi.tums.ac.ir

Recruitment status
Recruitment complete

Funding source

Expected recruitment start date
2019-09-23, 1398/07/01

Expected recruitment end date

2020-03-19, 1398/12/29

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Evaluation of the effects of Three Methods of Tranexamic Acid Administration on post operative blood loss following total knee arthroplasty compared with the control group

Public title

Comparison of different methods of tranexamic acid administration on post operative blood loss

Purpose

Treatment

Inclusion/Exclusion criteria

Inclusion criteria:

Patients who scheduled to undergo a unilateral total knee arthroplasty

Exclusion criteria:

Cardiovascular diseases Cerebrovascular diseases Bleeding disorders Known allergy to tranexamic acid Receiving the anti-coagulant drugs History of thromboembolic disease

Age

No age limit

Gender

Both

Phase

3

Groups that have been masked

- Participant
- Investigator
- Outcome assessor
- Data analyser
- Data and Safety Monitoring Board

Sample size

Target sample size: **200**

Randomization (investigator's opinion)

Randomized

Randomization description

A computer-generated list was created by the blocks of 12 randomization method

Blinding (investigator's opinion)

Double blinded

Blinding description

The concealed envelopes were used to blind the surgeon and participants for the randomization sequences and opened by a orthopedic resident, who was not involved in the study.

Placebo

Not used

Assignment

Parallel

Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee

Ethics Committee of Kerman University of Medical Sciences

Street address

Afzalipour Hospital, Imam Khomeini Highway

City

kerman

Province

Kerman

Postal code

7616913911

Approval date

2018-09-30, 1397/07/08

Ethics committee reference number

IR.KMU.REC.1397.245

Health conditions studied

1

Description of health condition studied

Amount of bleeding following total knee arthroplasty

ICD-10 code

Z96.659

ICD-10 code description

Presence of unspecified artificial knee joint

Primary outcomes

1

Description

The amount of hemoglobin

Timepoint

Preoperatively, 24 hours postoperatively and in the morning discharge day

Method of measurement

Complete Blood Count (CBC) test

2

Description

Post-operative drained blood volume

Timepoint

48 hours after the operation

Method of measurement

Hemovac drain

Secondary outcomes

1

Description

Surgical site infection

Timepoint

48 hours postoperatively

Method of measurement

clinical examination

Intervention groups

1

Description

Intervention group: 10 mg/kg of intravenous tranexamic acid in 100 cc of normal saline will be administrated following wound closure. The drain will be clamped for an hour.

Category

Treatment - Drugs

2

Description

Intervention group: The articular space will be irrigated with 3 gr of tranexamic acid for 5 minutes before knee closure. The drain will be clamped for an hour.

Category

Treatment - Drugs

3

Description

Intervention group: 1.5 gr of tranexamic acid will be delivered to the knee via the drain following wound closure. The drain will be clamped for an hour.

Category

Treatment - Drugs

4

Description

Control group: The drain will be clamped for an hour.

Category

Treatment - Drugs

Recruitment centers

1

Recruitment center

Name of recruitment center

Bahonar Hospital, Shafa Hospital

Full name of responsible person

Behnam Behmardi Kalantari

Street address

Bahonar Hospital, Qaraney St.

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Kerman

Province

Kerman

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7613747181

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pardis_sasani@yahoo.com

Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Kerman University of Medical Sciences

Full name of responsible person

Dr Abbas Pardakhti

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Ebne Sina St., Somayeh Intersection, Deputy of research and technology

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abpardakhty@kmu.ac.ir

Grant name

Grant code / Reference number

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

Yes

Title of funding source

Kerman 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

Kerman University of Medical Sciences

Full name of responsible person

Behnam Behmardi Kalantari

Position

Orthopedic Resident

Latest degree

Medical doctor

Other areas of specialty/work

Orthopedics

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Person responsible for scientific inquiries

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Person responsible for updating data

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Sharing plan

Deidentified Individual Participant Data Set (IPD)
Undecided - It is not yet known if there will be a plan to make this available
Study Protocol
Undecided - It is not yet known if there will be a plan to make this available
Statistical Analysis Plan
Not applicable
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
Not applicable
Data Dictionary
Not applicable