

# Clinical Trial Protocol

## Iranian Registry of Clinical Trials

10 Jun 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)

##### Phone

+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.

**City**

Kerman

**Province**

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**Postal code**

7613747181

**Phone**

+98 34 3212 2405

**Email**

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

**Street address**

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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Bahonar Hospital, Qaraney St

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## Person responsible for scientific 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**  
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## Person responsible for updating data

### Contact

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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