

Clinical Trial Protocol

Iranian Registry of Clinical Trials

28 Jun 2026

Comparison of the efficacy of oral, intravenous and topical Tranexamic acid in reducing bleeding after total knee arthroplasty

Protocol summary

Study aim

Comparison of the efficacy of oral, intravenous and topical tranexamic acid in reducing bleeding after total knee arthroplasty

Design

This study is clinical trial and double blind. 135 patients candidate arthroplasty referring to Amiralmomenin hospital and Vali Asr hospital in Arak will enter this study. We will divide patients in 3 groups randomly.

Settings and conduct

This study is clinical trial and double blind. 135 patients candidate arthroplasty referring to Amiralmomenin hospital and Vali Asr hospital in Arak will enter this study. Patients and outcome reviewer and analyzers are unaware of grouping. The study is double-blinded.

Participants/Inclusion and exclusion criteria

Patients undergoing total knee arthroplasty coming to Amiralmoemenin and Valiasr hospital in Arak; Patients between 30 and 80 years old; Patient with ASA class1 & ASA class2; Patients who have informed consent for presence in mentioned project; Patients who are operated by one surgeon; Operation time between 90 and 180 minutes

Intervention groups

We prescribe 10 milligram in kilogram Tranexamic acid by slow intravenous injection in first group. We prescribe 2 gram Tranexamic acid in 1000 milliliter normal saline by intra-articular in second group. We prescribe 1 gram Tranexamic acid oral and one dose in operation room in third group.

Main outcome variables

Mean of hemorrhage in postoperative; mean of hemorrhage during operation; return of patients with arthroplasty candidate to the operating room; mean of hemoglobin in postoperative

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20180411039272N1**
Registration date: **2018-06-10, 1397/03/20**
Registration timing: **registered_while_recruiting**

Last update: **2018-06-10, 1397/03/20**

Update count: **0**

Registration date

2018-06-10, 1397/03/20

Registrant information

Name

Shamim Valibak

Name of organization / entity

Country

Iran (Islamic Republic of)

Phone

+98 86 3417 3502

Email address

sh.valibak@arakmu.ac.ir

Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2018-04-23, 1397/02/03

Expected recruitment end date

2019-06-24, 1398/04/03

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Comparison of the efficacy of oral, intravenous and topical Tranexamic acid in reducing bleeding after total knee arthroplasty

Public title

Comparison of the efficacy of oral, intravenous and topical Tranexamic acid in reducing bleeding after total knee arthroplasty

Purpose

Treatment

Inclusion/Exclusion criteria

Inclusion criteria:

Patients undergoing total knee arthroplasty admitted in Amiralmoemenin and Valiasr hospital in Arak Patients between 30 and 80 years old Patient with ASA class1 and 2 Patients who have informed consent for presence in mentioned project Patients who are operated by one surgeon duration of operation time between 90 and 180 minutes

Exclusion criteria:

All Patients out rang of 30 to 80 years old Lack of Informed consent Patients with multiple surgeries Patients who are sensitive to Tranexamic acid Patients undergoing general anesthesia

Age

From **30 years** old to **80 years** old

Gender

Both

Phase

3

Groups that have been masked

- Participant
- Care provider
- Outcome assessor

Sample size

Target sample size: **135**

Randomization (investigator's opinion)

Randomized

Randomization description

Simple randomization with random number tables

Blinding (investigator's opinion)

Double blinded

Blinding description

Patients and outcome reviewer and analyzers are unaware of grouping. The study is double-blinded.

Placebo

Used

Assignment

Parallel

Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee

Ethics committe of Arak university of medical sciences

Street address

Vice chancellor for research, Payambar azam complex, Basij squre, Sardasht, Arak

City

Arak

Province

Markazi

Postal code

3848176941

Approval date

2018-02-25, 1396/12/06

Ethics committee reference number

IR.ARAKMU.REC.1396.293

Health conditions studied

1

Description of health condition studied

Total knee arthroplasty

ICD-10 code

T84.9

ICD-10 code description

Unspecified complication of internal orthopaedic prosthetic device, implant and graft

Primary outcomes

1

Description

Mean of bleeding in patients undergoing arthroplasty after operation

Timepoint

4 and 24 and 48 hours after operation

Method of measurement

Millileter

2

Description

Mean of bleeding during of operation

Timepoint

During of operation

Method of measurement

Millileter

3

Description

Number of come back again of patients to operation room

Timepoint

48 hours after operation

Method of measurement

Number

4

Description

Mean of hemoglobin

Timepoint

4 and 24 and 48 hours after operation

Method of measurement

Milligram in millileter

Secondary outcomes

empty

Intervention groups**1****Description**

Intervention group 1: We prescribe 10 milligram in kilogram Tranexamic acid by slow intravenous injection in first group.

Category

Treatment - Drugs

2**Description**

Intervention group 2: We prescribe 2 gram Tranexamic acid in 1000 milliliter normal salin by intra-articular in second group.

Category

Treatment - Drugs

3**Description**

Intervention group: We prescribe 1 gram Tranexamic acid oral and one dose in operation room in third group.

Category

Treatment - Drugs

Recruitment centers**1****Recruitment center****Name of recruitment center**

Amiralmoemenin hospital

Full name of responsible person

Shamim Valibak

Street address

Amiralmoemenin hospital, Basij square, Sardasht

City

Arak

Province

Markazi

Postal code

3848176941

Phone

+98 86 3417 3601

Fax

+98 86 3417 3619

Email

sh.valibak@arakmu.ac.ir

2**Recruitment center****Name of recruitment center**

Valiasr hospital

Full name of responsible person

Shamim valibak

Street address

Valiasr hospital, valiasr square

City

Arak

Province

Markazi

Postal code

3814957558

Phone

+98 86 3222 2003

Fax**Email**

sh.valibak@arakmu.ac.ir

Sponsors / Funding sources**1****Sponsor****Name of organization / entity**

Arak University of Medical Sciences

Full name of responsible person

Dr Mohammad Arjmandzadegan

Street address

Sardasht, Basij square, Payambare azam integrated university

City

Arak

Province

Markazi

Postal code

3848176941

Phone

+98 86 3417 3645

Fax

+98 86 3417 3639

Email

arjmandzadegan@arakmu.ac.ir

Grant name**Grant code / Reference number****Is the source of funding the same sponsor organization/entity?**

Yes

Title of funding source

Arak 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

Arak University of Medical Sciences

Full name of responsible person

Dr Hosseinali Hadi

Position

Assistant of professor

Latest degree

Specialist

Other areas of specialty/work

Orthopedics

Street address

Amiralmoemenin Hospital, Basij Square, Sardasht

Blvd., Arak Town

City

Arak

Province

Markazi

Postal code

3848176941

Phone

+98 86 3417 3502

Fax**Email**

Hadi@arakmu.ac.ir

Person responsible for scientific inquiries

Contact

Name of organization / entity

Arak University of Medical Sciences

Full name of responsible person

Dr Alireza Kamali

Position

Assistant of professor

Latest degree

Specialist

Other areas of specialty/work

Anesthesiology

Street address

Valiasr Hospital, Valiasr square, Shahid Shirodi street

City

Arak

Province

Markazi

Postal code

3848176941

Phone

+98 86 3417 3601

Fax**Email**

alikalaliir@yahoo.com

Person responsible for updating data

Contact

Name of organization / entity

Arak University of Medical Sciences

Full name of responsible person

Shamim Valibak

Position

Student of medical science

Latest degree

A Level or less

Other areas of specialty/work

General Practitioner

Street address

Payambar Azam Complex, Basij square, Sardasht,

Arak

City

Arak

Province

Markazi

Postal code

3848176941

Phone

+98 86 3417 3601

Fax**Email**

sh.valibak@arakmu.ac.ir

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

Yes - There is 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

Yes - There is a plan to make this available

Data Dictionary

Yes - There is a plan to make this available

Title and more details about the data/document

When we publish article in journal.

When the data will become available and for how long

After the article is published

To whom data/document is available

researcher in university

Under which criteria data/document could be used

If there are additional questions

From where data/document is obtainable

Dr Alireza Kamali

What processes are involved for a request to access data/document

They have to write letters to the professors and the university

Comments