

Clinical Trial Protocol

Iranian Registry of Clinical Trials

16 Sep 2026

Comparison of the Effect of Intravenous Tranexamic Acid on Reducing Postoperative Bleeding Volume in Patients with Complete Replacement of Knee Joint

Protocol summary

Study aim

Comparison of the Effect of Intravenous Tranexamic Acid on Reducing Postoperative Bleeding Volume in Patients with Complete Replacement of Knee Joint in Firoozgar Hospital during 2016 to 2018

Design

Two arm parallel group randomised trial with blinded

Settings and conduct

Subjects included patients who referred to Firoozgar Hospital clinic with knee pain. Based on the severity of articular cartilage destruction, candidates for knee arthroplasty were selected early and placed on the practice list. The drug was administered in two ways: intra-articular and intravenous. Intravenous injection was performed 30 minutes before surgery and intra-articular injection was performed intra-articularly and after arthroplasty. Postoperative blood volume and intraoperative hemoglobin were measured and compared. Blindness was single blind and patients were not aware of the injection method. But the surgeon and the research team were aware of the injection form.

Participants/Inclusion and exclusion criteria

Knee Osteoarthritis Age over 50 years Patient's consent to participate in the study Non-pregnancy and lactation Absence of acute and chronic renal failure No coagulation disorder proven There is definitive indication for primary knee replacement surgery

Intervention groups

This study was designed to evaluate the efficacy of tranexamic acid antifibrinolytic drug in Determination the mean bleeding volume of patients undergoing knee arthroplasty. In one group the drug is injected intravenously and in the other group intravenously. The results of the injection are compared between the two groups.

Main outcome variables

Mean amount of blood lost during and after surgery

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20190427043390N1**

Registration date: **2019-09-28, 1398/07/06**

Registration timing: **retrospective**

Last update: **2019-09-28, 1398/07/06**

Update count: **0**

Registration date

2019-09-28, 1398/07/06

Registrant information

Name

Ali Torkaman

Name of organization / entity

Country

Iran (Islamic Republic of)

Phone

+98 21 8214 1301

Email address

torkaman.a@iums.ac.ir

Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2016-09-22, 1395/07/01

Expected recruitment end date

2018-09-23, 1397/07/01

Actual recruitment start date

2016-09-28, 1395/07/07

Actual recruitment end date

2018-09-04, 1397/06/13

Trial completion date

2019-01-25, 1397/11/05

Scientific title

Comparison of the Effect of Intravenous Tranexamic Acid on Reducing Postoperative Bleeding Volume in Patients with Complete Replacement of Knee Joint

Public title

Tranexamic Acid in Total Knee Arthroplasty

Purpose

Treatment

Inclusion/Exclusion criteria

Inclusion criteria:

All patients with knee articular cartilage destruction that do not respond to supportive treatments

Exclusion criteria:

revision

Age

From **50 years** old

Gender

Both

Phase

2

Groups that have been masked

- Participant

Sample size

Target sample size: **80**

Actual sample size reached: **85**

Randomization (investigator's opinion)

Randomized

Randomization description

Our aim was to place patients in groups A (intravenous) and B (intra-articular). (AABB), (ABAB), (BAAB) and (BBAA) were plotted. These 4 blocks were placed in a closed door package, each of which was randomly removed. For the first 4 patients, one block was randomly removed from the envelope, and the order of the patients in the two groups followed the order of the removed block.

Blinding (investigator's opinion)

Single blinded

Blinding description

Failure to inform patients about the type of injection

Placebo

Not used

Assignment

Parallel

Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee

Ethics committee of Iran University of Medical Sciences, Vice chancellor for research, Faculty of Me

Street address

Iran University of Medical Sciences, Hemmat

Highway, Next to Milad Tower

City

Tehran

Province

Tehran

Postal code

۱۴۴۹۶۱۴۵۳۵

Approval date

2017-05-14, 1396/02/24

Ethics committee reference number

IR.IUMS.FMD.REC1396.9411242008

Health conditions studied

1

Description of health condition studied

primary osteoarthritis

ICD-10 code

M15.0

ICD-10 code description

Primary generalized (osteo)arthrosis

Primary outcomes

1

Description

Average amount of blood lost

Timepoint

During and after surgery

Method of measurement

Graduated cylinders in milliliters

Secondary outcomes

1

Description

deep vein thrombosis , thromboembolism

Timepoint

during 3 month post-surgical

Method of measurement

physical examination

Intervention groups

1

Description

Intervention group: Intravenous injection of one gram of single dose tranexamic acid, during ten minutes before surgery

Category

Treatment - Drugs

2

Description

Intervention group: Intervention group: intra-articular injection of one gram of single dose tranexamic acid, 10

minutes before surgery
Category
Treatment - Drugs

Recruitment centers

1

Recruitment center

Name of recruitment center

Firoozgar hospital

Full name of responsible person

Ali Torkaman

Street address

Orthopedic Department, Firoozgar hospital, Beh afarin ave, Valiasr square

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Phone

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Email

Torkaman.a@iums.ac.ir

Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Vice chancellor for research, Iran University of Medical Sciences

Full name of responsible person

Dr. Seyed Abbas Motavallian

Street address

Shahid Hemmat West highway - between the intersection of Sheikh Fazlollah Nouri and Shahid Chamran

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

Yes

Title of funding source

Vice chancellor for research, Iran 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**

Iran University of Medical Sciences

Full name of responsible person

Ali torkaman

Position

Associate professor

Latest degree

Subspecialist

Other areas of specialty/work

Orthopedics

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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

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