

Clinical Trial Protocol

Iranian Registry of Clinical Trials

30 Jun 2026

Prophylactic effect of oral Tranexamic Acid on bleeding in knee replacement surgery

Protocol summary

Study aim

Determine the role of oral Tranexamic Acid prophylactic effect in the prevention of bleeding surgery for knee replacement

Design

This clinical trial is based on community-based and pragmatic control group with parallel groups. Patients are divided into two groups by simple random sampling .Sample size is 30 patients who are candidates for knee replacement surgery

Settings and conduct

This study was performed on patients undergoing knee replacement surgery at Khatam-ol-Anbia Sharood Hospital.

Participants/Inclusion and exclusion criteria

Entry requirements: 1.The patient has a specific disease history such as kidney disease, liver disease, history of myocardial ischemia, hypertension, history of brain ischemia, and thromboembolic events. 2.Patients do not use aspirin or any other anticoagulants from the week prior to surgery: Plavix, Heparin, Enoxaparin, Warfarin. 3.Do not observe a specific diet (not just vegetarian or non-meat-eaters or use of certain substances that can interfere with blood parameters) 4.The patient do not use certain medications, such as supplements, iron and other drugs associated with blood tests. Exclusion criteria: 1.Patient dissatisfaction to continue participation 2.Patients with abnormal clotting parameters (PT, PTT, BT, INR, platelet) 3.People with high systolic blood pressure (185 on the day of surgery) 4. During surgery and up to 6 hours after the operation, the osmotic arterial pressure is more than 20%.

Intervention groups

The intervention group: consisted of 15 patients who took oral capsules of 250 mg Tranexamic Acid every 6 hours. They used a total of 2 g before surgery. The control group: included 15 patients entered the study according to entry criteria and get only routine care.

Main outcome variables

Bleeding during and after surgery.

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20190220042773N1**

Registration date: **2019-04-09, 1398/01/20**

Registration timing: **registered_while_recruiting**

Last update: **2019-04-09, 1398/01/20**

Update count: **0**

Registration date

2019-04-09, 1398/01/20

Registrant information

Name

aboutaleb safdari

Name of organization / entity

Country

Iran (Islamic Republic of)

Phone

+98 23 3239 7627

Email address

aboutaleb.safdari@yahoo.com

Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2019-03-16, 1397/12/25

Expected recruitment end date

2019-07-16, 1398/04/25

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Prophylactic effect of oral Tranexamic Acid on bleeding in knee replacement surgery

Public title

Prophylactic effect of oral Tranexamic Acid on bleeding in knee replacement surgery

Purpose

Prevention

Inclusion/Exclusion criteria

Inclusion criteria:

The patient's full conditions for participation in the study and signature of the prepared form of the informed consent A person with a history of specific disease, such as kidney disease, liver disease, history of ischemia, heart, hypertension, history of self-sacrifice and signs of disability in the diagnosis and treatment of disability. Patients do not use aspirin or any other anticoagulants from the week before surgery: Plavix, heparin, enoxaparin, and warfarin. Do not observe a specific diet (it's not just herbivorous or meat-eaters, or the use of certain substances that lower blood glucose levels) Do not use special medication such as iron or other medications associated with bleeding.

Exclusion criteria:

Patient dissatisfaction to continue participation Patients with abnormal clotting parameters (PT, PTT, BT, INR, platelet) People with high systolic blood pressure (185 in surgery day) During surgery and up to 6 hours after the operation, the osmotic arterial pressure is more than 20%. Patients with complications such as nausea and vomiting, color blindness, headache and dizziness, thromboemboli, myocardial ischemia and nutritional ischemia before and after surgery.

Age

No age limit

Gender

Both

Phase

4

Groups that have been masked

No information

Sample size

Target sample size: 30

Randomization (investigator's opinion)

Not randomized

Randomization description

Blinding (investigator's opinion)

Not blinded

Blinding description

Placebo

Not used

Assignment

Parallel

Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee

Ethics Committee of Islamic Azad University, Shahrood Branch

Street address

Shahrood, Shahr Branch, Islamic Azad University, Shahr

City

Shahrood

Province

Semnan

Postal code

43189- 36199

Approval date

2019-03-09, 1397/12/18

Ethics committee reference number

IR.IAU.SHAHROOD.REC.1397.038

Health conditions studied

1

Description of health condition studied

Joint knee replacement hemorrhage

ICD-10 code

ICD-10 code description

Primary outcomes

1

Description

Volume of bleeding in knee replacement surgery

Timepoint

During surgery and 6 hours after surgery and 12 hours after knee replacement

Method of measurement

Level of hemoglobin and platelets, PT, PTT, BT before and after the operation, the amount of blood lost through surgical suction bottles, weighing the used gauzes during surgery and blood on the field of postoperative surgery patients

Secondary outcomes

empty

Intervention groups

1

Description

The intervention group: consisted of 15 patients who took oral capsules of 250 mg Tranexamic Acid every 6 hours They used a total of 2 g 2 day before knee replacement surgery.

Category

Prevention

2

Description

Control group : included 15 patients candidate knee replacement surgery entered the study according to entry criteria And doing no extra work

Category

Prevention

Recruitment centers

1

Recruitment center

Name of recruitment center

Khatam Al-Anbia Hospital in Shahrood

Full name of responsible person

Aboutaleb Safdari

Street address

Shahrood, University of Blvd., Shahrood Islamic Azad University

City

Shahrood

Province

Semnan

Postal code

43189- 36199

Phone

+98 23 3239 0077

Fax

Email

aboutaleb.safdari@yahoo.com

Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Islamic Azad University

Full name of responsible person

Aboutaleb Safdari

Street address

Shahrood, University of Blvd., Shahrood Islamic Azad University

City

Shahrood

Province

Semnan

Postal code

36199-43189

Phone

+98 23 3239 0077

Email

aboutaleb.safdari@yahoo.com

Grant name

Grant code / Reference number

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

Yes

Title of funding source

Islamic Azad University

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

Islamic Azad University

Full name of responsible person

Dr Yousef Kolookhi

Position

Assistant Professor

Latest degree

Specialist

Other areas of specialty/work

Anesthesiology

Street address

Shahrood, University of Blvd., Shahrood Islamic Azad University

City

Shahrood

Province

Semnan

Postal code

36199-43189

Phone

+98 23 3239 0077

Email

dryousefkolookhianestezi@gmail.com

Person responsible for scientific inquiries

Contact

Name of organization / entity

Islamic Azad University

Full name of responsible person

Dr Yousef Kolookhi

Position

Associate professor

Latest degree

Specialist

Other areas of specialty/work

Anesthesiology

Street address

Shahrood, University of Blvd., Shahrood Islamic Azad University

City

Shahrood

Province

Semnan

Postal code

36199-43189

Phone

+98 23 3239 0077

Email

dryousefkolookhianestezi@gmail.com

36199-43189

Phone

+98 23 3239 0077

Email

aboutaleb.safdari@yahoo.com

Person responsible for updating data**Contact****Name of organization / entity**

Islamic Azad University

Full name of responsible person

Aboutaleb Safdari

Position

Medical Student

Latest degree

A Level or less

Other areas of specialty/work

General Practitioner

Street address

Shahrood, University of Blvd., Shahrood Islamic Azad University

City

Shahrood

Province

Semnan

Postal code**Sharing plan****Deidentified Individual Participant Data Set (IPD)**

No - There is not a plan to make this available

Justification/reason for indecision/not sharing IPD

Given the importance of protecting the privacy of patients if they hide patient information and merely inform potential cases

Study Protocol

No - There is not a plan to make this available

Statistical Analysis Plan

Not applicable

Informed Consent Form

No - There is not a plan to make this available

Clinical Study Report

Not applicable

Analytic Code

Not applicable

Data Dictionary

Not applicable