

Clinical Trial Protocol

Iranian Registry of Clinical Trials

20 Jul 2026

measuring The effect of tranexamic acid injection during anterior cruciate ligament reconstruction surgery on postoperative bleeding, pain and swelling

Protocol summary

Study aim

Determining the effect of transamine acid injection during anterior cruciate ligament reconstruction surgery on postoperative bleeding, pain and swelling after surgery

Design

Clinical trial with control group, with parallel groups, double-blind, randomized, phase 2 on 60 patients.

Settings and conduct

Patients who have referred to Al-Zahra and Kashani hospitals in Isfahan city for anterior cruciate ligament repair surgery are placed in two random groups and one group is injected with tranexamic acid and the other group with normal saline during surgery. The range of motion of the knee joint, the amount of pain, swelling, and degree of hemarthrosis are evaluated before surgery. After surgery, the drain output is measured in the first 24 hours. Also, the amount of pain, swelling and degree of hemarthrosis in the first 24 hours, the third day and one month after surgery and the range of motion and functional score of the knee one month after surgery are evaluated. Pain is measured using the Visual Analogue Scale (VAS). Patients and the person receiving postoperative care are unaware of the drug injection or placebo.

Participants/Inclusion and exclusion criteria

Inclusion criteria: Anterior cruciate ligament rupture
Exclusion criteria: Having any type of coagulation disorder; Rheumatic disease; Previous surgical history; Severe swelling of the joint before surgery

Intervention groups

The first study group receiving 15 mg / kg tranxamic acid per 100 cc of normal saline before opening the tourniquet. In the second group, only normal saline is injected in the same volume from the first group.

Main outcome variables

Joint pain; range of motion of the joint; Inflation;

Hemarthrosis; Drain output; Knee functional score

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20201015049033N1**

Registration date: **2021-05-12, 1400/02/22**

Registration timing: **prospective**

Last update: **2021-05-12, 1400/02/22**

Update count: **0**

Registration date

2021-05-12, 1400/02/22

Registrant information

Name

reza entezari

Name of organization / entity

Country

Iran (Islamic Republic of)

Phone

+98 31 3629 4247

Email address

drreza.ent@gmail.com

Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2021-09-23, 1400/07/01

Expected recruitment end date

2023-03-20, 1401/12/29

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

measuring The effect of tranexamic acid injection during anterior cruciate ligament reconstruction surgery on postoperative bleeding, pain and swelling

Public title

measuring The effect of tranexamic acid injection during anterior cruciate ligament reconstruction surgery

Purpose

Supportive

Inclusion/Exclusion criteria**Inclusion criteria:**

Informed consent Anterior cruciate ligament rupture

Exclusion criteria:

Having coagulation diseases Rheumatic diseases of the joints History of previous knee joint surgery Receive anticoagulant therapy before surgery Coagulation profile disorder before surgery Cycle cell anemia Sensitivity to tranexamic acid Severe swelling of the joint before surgery

Age

No age limit

Gender

Both

Phase

3

Groups that have been masked

- Participant
- Outcome assessor

Sample size

Target sample size: 60

Randomization (investigator's opinion)

Randomized

Randomization description

Simple and individual randomization method is done through a random numbers table and The group of patients is given to the operating room nurse to prepare the medicine or placebo for injection. First we defined the framework of our statistical community and randomly started from a point in the table in the direction of the row or column. Depending on the type of code, we selected the same number of digits in the row or column direction. We continued this work until the number of samples was completed. even numbers were used for the intervention group and individual numbers for the control group.

Blinding (investigator's opinion)

Double blinded

Blinding description

The patients has no knowledge of injecting medication or placebo during surgery. A person who monitors the amount of drainage, the degree of hemarthrosis, the range of motion of the knee joint, and the amount of pain and swelling has no knowledge of injecting medication or placebo during surgery.

Placebo

Used

Assignment

Parallel

Other design features**Secondary Ids**

empty

Ethics committees**1****Ethics committee****Name of ethics committee**

Ethics committee of Isfahan University of Medical Sciences

Street address

shohada sofe Ave., Al-zahra hospital

City

Isfahan

Province

Isfahan

Postal code

8173815796

Approval date

2021-02-07, 1399/11/19

Ethics committee reference number

IR.MUI.MED.REC.1399.1028

Health conditions studied**1****Description of health condition studied**

Anterior cruciate ligament rupture

ICD-10 code

S83.5

ICD-10 code description

Sprain of cruciate ligament of knee

Primary outcomes**1****Description**

joint pain

Timepoint

Before surgery, the first 24 hours after surgery and on the third day and the first month after surgery

Method of measurement

Visual analogue scale (VAS)

2**Description**

Range of motion of the knee joint

Timepoint

Before surgery and one month after surgery

Method of measurement

angle

3

Description

Hemarthrosis

Timepoint

Before surgery, the first 24 hours after surgery and on the third day and the first month after surgery

Method of measurement

check list

4

Description

Drain output

Timepoint

The first 24 hours after surgery

Method of measurement

volume in cc

5

Description

Knee functional score

Timepoint

one month after surgery

Method of measurement

score

Secondary outcomes

empty

Intervention groups

1

Description

Intervention group: During anterior cruciate ligament repair surgery, 15 mg / kg tranexamic acid into 100 cc of normal saline is injected before opening the tourniquet.

Category

Rehabilitation

2

Description

Control group: During anterior cruciate ligament surgery in the control group with the same volume as the intervention group, normal saline is injected before opening the tourniquet.

Category

Placebo

Recruitment centers

1

Recruitment center

Name of recruitment center

Al-Zahra Hospital of Isfahan

Full name of responsible person

Reza Entezari

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Shohada Sofe Ave.

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2

Recruitment center

Name of recruitment center

Kashani Hospital of Isfahan

Full name of responsible person

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Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Esfahan University of Medical Sciences

Full name of responsible person

Saghayegh Haghjoo Javanmard

Street address

Al-Zahra Hospital

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Grant name

Grant code / Reference number

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

Yes

Title of funding source

Esfahan 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**

Esfahan University of Medical Sciences

Full name of responsible person

Reza Entezari

Position

Resident

Latest degree

Medical doctor

Other areas of specialty/work

Orthopedics

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Person responsible for scientific inquiries**Contact****Name of organization / entity**

Esfahan University of Medical Sciences

Full name of responsible person

Hamid Mousavi

Position

Associate professor

Latest degree

Specialist

Other areas of specialty/work

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

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Resident

Latest degree

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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

Not applicable

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

Not applicable

Data Dictionary

Not applicable

Title and more details about the data/document

Patient information including patient age and preoperative findings and postoperative outcomes that are relevant to the study and the type of drug injected into the patient can be disseminated.

When the data will become available and for how long

Six months after the results were published

To whom data/document is available

The data will be available only to researchers working in academic and scientific institutions.

Under which criteria data/document could be used

Data are provided for similar studies and other statistical analyzes.

From where data/document is obtainable

To receive information, send an email to the following address: drreza.ent@gmail.com

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

About two months after the email is sent and the data is

verified.

Comments