

Clinical Trial Protocol

Iranian Registry of Clinical Trials

25 Jun 2026

The effectiveness of topical tranexamic acid compare to injection into the clamp drain on the bleeding after knee arthroplasty surgery

Protocol summary

Summary

According to problems of bleeding in knee Arthroplasty surgery patients, the aim of this study is to determine the effect of local injection of transamic acid compare to into drain injection in arthroplasty patients. In this study , 75 patients will be selected randomly. Inclusion criteria : 18-85 years old patients who have arthroplasty surgery exclusion criteria : patients who have secondary osteoarthritis like rheumatoid arthritis and arthritis following by trauma and gout and arthritis following by joint infection. Patients will be divided in 3 groups by random. First group will get placebo in their clamped drain, in second group transamic acid will be injected in their clamped drain and the third group will get transamic acid as local injection. All the surgeries will be done by one specialist surgeon. Patients, surgeon and data collectors will be blinded. Hemoglobin will be measured before and 12-8-4 hours after surgery and according to above protocol , a decisions was made. All patients will be releasing 5 days after surgery.

General information

Acronym

IRCT registration information

IRCT registration number: **IRCT2016122730123N1**

Registration date: **2016-12-27, 1395/10/07**

Registration timing: **retrospective**

Last update:

Update count: **0**

Registration date

2016-12-27, 1395/10/07

Registrant information

Name

Ehsan Golkar Khozani

Name of organization / entity

Shahid Sadoughi University Of Medical Sciences

Country

Iran (Islamic Republic of)

Phone

+98 35 3828 6389

Email address

e.golkar@ssu.ac.ir

Recruitment status

Recruitment complete

Funding source

Shahid Sadoughi University of medical Sciences accepted to supply drug for this study

Expected recruitment start date

2016-11-16, 1395/08/26

Expected recruitment end date

2016-12-15, 1395/09/25

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

The effectiveness of topical tranexamic acid compare to injection into the clamp drain on the bleeding after knee arthroplasty surgery

Public title

The effectiveness of topical tranexamic acid compare to injection into the clamp drain on the bleeding after knee arthroplasty surgery

Purpose

Treatment

Inclusion/Exclusion criteria

Inclusion criteria : Adults age between 18- 85 years; patients who need artheroplasty Exclusion criteria: Secondary artheritis like rheumatoid artheritis; traumatic artheritis; gout; infectious artheritis ; patients with chronic disease (ischemic cardiopathy, nocturnal apnea

syndrome, severe pulmonary disease, chronic renal failure, liver failure, and ...; History of thromboembolic disease (platelet under 150000 in milimeter, INR upper 1.4, and PTT 1.4 upper than normal ratio; hemorrhagic disease; allergy to tranxamic acid; anticoagulant drug users

Age

From **18 years** old to **85 years** old

Gender

Both

Phase

3

Groups that have been masked

No information

Sample size

Target sample size: **75**

Randomization (investigator's opinion)

Randomized

Randomization description**Blinding (investigator's opinion)**

Triple blinded

Blinding description**Placebo**

Used

Assignment

Parallel

Other design features**Secondary Ids**

empty

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

Ethical Committee of Shahid Sadoughi Faculty of Medicine, Yazd

Street address

Faculty of Medicine, Shahid Sadoughi University of Medical Sciences, Shohadaye Gomnam blv, Professor Hesabi blv, Yazd

City

Yazd

Postal code**Approval date**

2016-05-01, 1395/02/12

Ethics committee reference number

ir.ssu.medicine.rec.1395.17

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

Arthrosis of Knee

ICD-10 code

M17.0

ICD-10 code description

Primary gonarthrosis, bilateral

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

Hemoglobin level of blood

Timepoint

12 and 48 hour after surgery

Method of measurement

Grams of hemoglobin per deciliter blood with full automatic laboraty devices

Secondary outcomes**1****Description**

Deep vein thrombosis

Timepoint

During the hospitalization of patients and during post operational follow up of pateints

Method of measurement

Physical examination and medical history of pateint

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

Control: 30 ml of normal saline will use in drain and drain will be clamp

Category

Treatment - Drugs

2**Description**

Intervention1: 15 mg tranexamic acid before closure of the wound and 15 mg tranexamic acid after closure of skin will use

Category

Treatment - Drugs

3**Description**

Intervention2: 30 ml normal saline with 3mg tranexamic acid will use for 3 hour after clamp of drain.

Category

Treatment - Drugs

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

Shahid Sadoughi Hospital, Yazd

Full name of responsible person

Ehsan Golkar Khozany

Street address

Shahid Sadoughi Hospital, Shahid Ghandi street,
Safaie, Yazd

City

Yazd

Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Shahid Sadoughi University of Medical Sciences

Full name of responsible person

Vice Chancellor Of Research, Shahid Sadoughi
University of Medical Sciences

Street address

Central Administration, Bahonar Sq., Yazd, Iran

City

Yazd

Grant name

Grant code / Reference number

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

Yes

Title of funding source

Shahid Sadoughi University of Medical Sciences

Proportion provided by this source

100

Public or private sector

empty

Domestic or foreign origin

empty

Category of foreign source of funding

empty

Country of origin

Type of organization providing the funding

empty

Person responsible for general inquiries

Contact

Name of organization / entity

Shahid Sadoughi University of Medical Sciences

Full name of responsible person

Ehsan Golkar Khozany

Position

MD, Assistant of Ortheopedics

Other areas of specialty/work

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Person responsible for updating data

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Sharing plan

Deidentified Individual Participant Data Set (IPD)

empty

Study Protocol

empty

Statistical Analysis Plan

empty

Informed Consent Form

empty

Clinical Study Report

empty

Analytic Code

empty

Data Dictionary

empty