

# Clinical Trial Protocol

## Iranian Registry of Clinical Trials

24 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 Gornam 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**

**Street address**

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**Web page address**

## Person responsible for scientific inquiries

**Contact**

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## Person responsible for updating data

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**Other areas of specialty/work**

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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*