

# Clinical Trial Protocol

## Iranian Registry of Clinical Trials

29 Jun 2026

### The effect of thromboprophylactic drugs on post-operative complications of arthroscopic ACL reconstruction surgery

#### Protocol summary

##### Study aim

The effects of aspirin and enoxapirin with the control group in prevention of DVT, PTE, hemarthrosis, trombololphyllaxy after arthroscopy ACL construction surgery

##### Design

Single center, 3 parallel groups, randomized trial with blinded, on 138 patients. random allocation software was used to randomization.

##### Settings and conduct

This study is being performed at Taleghani Hospital. Patients follow up continues for 4 weeks after surgery. To check out pTE used to weekly examination for 4 weeks and current description will be taken and in suspicious cases used CT angiography with contrast. To check out the DVT before surgery, during the release and 4 weeks after the release, bilateral doppler sonography of the lower body will be done. But the examination of DVT symptoms done weekly, and at any time of follow up if incidence warning symptoms bilateral doppler sonography of the lower body will be done for patient. The strong test is used to check out the effusion and hemarthrosis, with the score as per the results of the examination and included in an open range of 0 to 3. From the beginning of the study, groups were identified by name and code, and the patient, the physician, data collector and Data analysis specialist were blind about grouping.

##### Participants/Inclusion and exclusion criteria

Patients with ACL rupture diagnosed in MRI entered the study. Age under 18 and over 45 year old, BMI over 30, other ligament damage, the same side damage, smokers, have a DVT history, cancer or active infection, have anemia, allergy to aspirin or enoxapirin, background of coagulation disorders will be excluded from our study.

##### Intervention groups

Intervention 1: aspirin daily for 14 days Intervention 2: prescribed SQ injection of enoxapirin for 14 days Control:

receive none of anticoagulant drug as a control group.

##### Main outcome variables

DVT: PTE: effusion: hemarthrosis.

#### General information

##### Reason for update

##### Acronym

##### IRCT registration information

IRCT registration number: **IRCT20170807035554N2**

Registration date: **2020-06-21, 1399/04/01**

Registration timing: **retrospective**

Last update: **2020-06-21, 1399/04/01**

Update count: **0**

##### Registration date

2020-06-21, 1399/04/01

##### Registrant information

##### Name

arash sajadi

##### Name of organization / entity

shaheed beheshti university of medical science

##### Country

Iran (Islamic Republic of)

##### Phone

+98 912 337 7215

##### Email address

arashsajadi@sbm.ac.ir

##### Recruitment status

**Recruitment complete**

##### Funding source

##### Expected recruitment start date

2020-06-09, 1399/03/20

##### Expected recruitment end date

2020-06-09, 1399/03/20

##### Actual recruitment start date

empty

**Actual recruitment end date**

empty

**Trial completion date**

empty

**Scientific title**

The effect of thromboprophylactic drugs on post-operative complications of arthroscopic ACL reconstruction surgery

**Public title**

The effect of thromboprophylactic drugs on post-operative complications of arthroscopic ACL surgery

**Purpose**

Treatment

**Inclusion/Exclusion criteria****Inclusion criteria:**

Patients between 18 and 45 years old Patient with ACL rupture diagnosed in MRI Entered the study

**Exclusion criteria:**

Patients with other ligament injuries in addition to ACL  
Patients with concomitant damage in the same side long osseous  
Patients who need other procedures that interfere With rehabilitation after surgery  
Having a history of DVT  
Patient who were under thromboprophylaxis before surgery

**Age**

From **18 years** old to **45 years** old

**Gender**

Both

**Phase**

N/A

**Groups that have been masked**

- Participant
- Investigator
- Outcome assessor
- Data analyser
- Data and Safety Monitoring Board

**Sample size**

Target sample size: **138**

**Randomization (investigator's opinion)**

Randomized

**Randomization description**

The randomization for 2 intervention groups an 1 control group. The randomization method will done using software, 46 random numbers for each intervention group. The researcher can not play a role in predicting treatment of the disease, and choosing the type of treatment. random sequence will generate by software. All 138 Admitted individuals fall into one of three groups according to a predetermined code

**Blinding (investigator's opinion)**

Triple blinded

**Blinding description**

In this study, blinding is performed at three levels: patient, physician, and data analyzer; So that the drugs are packaged and coded in dark paper packages. As a result, the patient, physician, and person in charge of the analysis are not informed of the type of medication prescribed.

**Placebo**

Not used

**Assignment**

Parallel

**Other design features****Secondary Ids**

empty

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

Shahid Beheshti university of medical science

**Street address**

Shahid Beheshti University of Medical Sciences, Yemen St., Arabi St., Chamran Highway

**City**

Tehran

**Province**

Tehran

**Postal code**

1985717434

**Approval date**

2019-11-09, 1398/08/18

**Ethics committee reference number**

IR.SBMU.MSP.REC.1398.791

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

post-operative complications of arthroscopic ACL reconstruction

**ICD-10 code**

S83.7

**ICD-10 code description**

Injury to multiple structures of knee

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

Deep vein thrombosis (DVT)

**Timepoint**

14 and 28 days after surgery

**Method of measurement**

With examination and Doppler ultrasound

**2****Description**

Venous thromboembolism (VTE)

**Timepoint**

14 and 28 days after surgery

**Method of measurement**

with contrast methods and computed tomography (ct angiography)

### 3

**Description**

hemarthrosis and opioids

**Timepoint**

14 and 28 days after surgery

**Method of measurement**

Examination methods and score according to the stroke table

### 4

**Description**

Intraspinal bleeding

**Timepoint**

14 and 28 days after surgery

**Method of measurement**

Examination

### 5

**Description**

Operative bleeding

**Timepoint**

14 and 28 days after surgery

**Method of measurement**

Examination

### 6

**Description**

Retroperitoneal bleeding

**Timepoint**

14 and 28 days after surgery

**Method of measurement**

Examination

## Secondary outcomes

empty

## Intervention groups

### 1

**Description**

Intervention group: (1) start up 80 mg aspirin daily for 14 days

**Category**

Treatment - Drugs

### 2

**Description**

Intervention group: (2) prescribed SQ injection of enoxapirin 40 for 14 days

**Category**

Treatment - Drugs

### 3

**Description**

Control: receive none of anticoagulant drug as a control group

**Category**

Treatment - Drugs

## Recruitment centers

### 1

**Recruitment center****Name of recruitment center**

Taleghani hospital

**Full name of responsible person**

Mohammadreza Minator Sajjadi

**Street address**

Next to Shahid Beheshti University of Medical Sciences, Yemen St., Arabi St., Chamran highway.

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arashsajadi@sbmu.ac.ir

## Sponsors / Funding sources

### 1

**Sponsor****Name of organization / entity**

Taleghani Hospital Research Development committee

**Full name of responsible person**

Mahshid Mehdipour

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Next to Shahid Beheshti University of Medical Sciences, Yemen St., Arabi St., Chamran highway.

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arashsajadi@sbmu.ac.ir

**Grant name**

Not used

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

Yes

**Title of funding source**

Taleghani Hospital Research Development committee

**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

## 2

### **Sponsor**

**Name of organization / entity**  
Shahid Beheshti University of Medical Sciences  
**Full name of responsible person**  
Afshin Zarghi  
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### **Grant name**

No

### **Grant code / Reference number**

خير

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

Yes

### **Title of funding source**

Shahid Beheshti 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**  
Shahid Beheshti University of Medical Sciences  
**Full name of responsible person**  
Mohammadreza Minator Sajjadi  
**Position**  
Associate professor  
**Latest degree**  
Subspecialist  
**Other areas of specialty/work**

Orthopedics  
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## **Person responsible for scientific inquiries**

### **Contact**

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**Latest degree**  
Subspecialist  
**Other areas of specialty/work**  
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## **Person responsible for updating data**

### **Contact**

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Shahid Beheshti University of Medical Sciences  
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**Position**  
Assistant professor  
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Subspecialist  
**Other areas of specialty/work**  
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okhovatpour@sbmu.ac.ir

## 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**

Yes - There is a plan to make this available

### **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**

Yes - There is a plan to make this available

### **Data Dictionary**

Yes - There is a plan to make this available

### **Title and more details about the data/document**

All data can be shared potentially after patients became unrecognizable

### **When the data will become available and for how long**

After completing the results and analyzing the data, access to them is allowed

### **To whom data/document is available**

This is only available for people working in academic institutions

### **Under which criteria data/document could be used**

This is only available for people working in academic institutions

### **From where data/document is obtainable**

After obtaining written permission, the use of the data is permitted with reference to the source. Dr Mohammadreza Sajjadi, 09123377215

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

After completing the results and analyzing the data, the use of the data is allowed after the written request.

### **Comments**