

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.

City

Tehran

Province

Tehran

Postal code

1985711151

Phone

+98 21 2243 2020

Email

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

Street address

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

City

Tehran

Province

Tehran

Postal code

1985711151

Phone

+98 21 2243 2560

Fax**Email**

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
Street address
Next to Shahid Beheshti University of Medical Sciences, Yemen St., Arabi St., Chamran highway.
City
tehran
Province
Tehran
Postal code
1985711151
Phone
+98 21 2243 2560
Fax
+98 21 2243 2560
Email
arashsajadi@sbmu.ac.ir

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
Street address
Taleghani hospital, next to Shahid Beheshti University of Medical Sciences, Yemen St., Arabi St., Chamran Highway
City
Tehran
Province
Tehran
Postal code
1985711151
Phone
+98 21 2240 2020
Email
arashsajadi@sbmu.ac.ir

Person responsible for scientific 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
Street address
Taleghani hospital, next to Shahid Beheshti University of Medical Sciences, Yemen St., Arabi St., Chamran Highway
City
Tehran
Province
Tehran
Postal code
1985711151
Phone
0098 22402020
Email
arashsajadi@sbmu.ac.ir

Person responsible for updating data

Contact

Name of organization / entity
Shahid Beheshti University of Medical Sciences
Full name of responsible person
Mohammadreza Minator Sajjadi
Position
Assistant professor
Latest degree
Subspecialist
Other areas of specialty/work
Orthopedics
Street address
Shahid Beheshti University of Medical Sciences, Yemen St., Arabi St., Chamran highway.
City

Tehran
Province
Tehran
Postal code
1985717443
Phone
+98 21 2240 2020
Email
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