

# Clinical Trial Protocol

## Iranian Registry of Clinical Trials

04 Aug 2026

### Evaluation of the Two Different Enoxaparin Regimen in the Prophylaxis of Deep Venous Thrombosis

#### Protocol summary

##### Study aim

Evaluation of the two different enoxaparin regimen in prophylaxis for deep venous thrombosis

##### Design

Clinical trial with control group on 60 patients, block randomization was used.

##### Settings and conduct

Loghman Hakim Hospital, Tehran

##### Participants/Inclusion and exclusion criteria

In this study, patients who are between 18 and 65 years old and are candidate for receiving enoxaparin for prophylaxis of deep vein thrombosis included. Those patients who are in critically state or at hemorrhage risk will be excluded.

##### Intervention groups

Patients in group one receive pre-filled syringes of enoxaparin (manufactured by Alborz Daroo company) at dose of 40 mg/day through subcutaneous route and patients in group two receive pre-filled syringes of enoxaparin (manufactured by Alborz Daroo company) at dose of 1 mg/kg/day through subcutaneous route.

##### Main outcome variables

The activity level of anti-Xa, occurrence rate of venous thromboembolism, occurrence rate of adverse drug reactions.

#### General information

##### Reason for update

##### Acronym

##### IRCT registration information

IRCT registration number: **IRCT20130917014693N11**

Registration date: **2020-05-18, 1399/02/29**

Registration timing: **retrospective**

Last update: **2020-05-18, 1399/02/29**

Update count: **0**

##### Registration date

2020-05-18, 1399/02/29

##### Registrant information

###### Name

Zahra Sahraei

###### Name of organization / entity

Faculty of pharmacy, Shahid beheshti university of medical sciences

###### Country

Iran (Islamic Republic of)

###### Phone

+98 21 8887 3704

###### Email address

z.sahraei@sbmu.ac.ir

##### Recruitment status

###### Recruitment complete

##### Funding source

##### Expected recruitment start date

2018-07-23, 1397/05/01

##### Expected recruitment end date

2020-02-20, 1398/12/01

##### Actual recruitment start date

2018-07-23, 1397/05/01

##### Actual recruitment end date

2020-02-20, 1398/12/01

##### Trial completion date

2020-03-19, 1398/12/29

##### Scientific title

Evaluation of the Two Different Enoxaparin Regimen in the Prophylaxis of Deep Venous Thrombosis

##### Public title

Evaluation of the Enoxaparin in the Prophylaxis of Deep Venous Thrombosis

##### Purpose

Treatment

##### Inclusion/Exclusion criteria

###### Inclusion criteria:

Age between 18 and 65 years old Padua risk score  $\geq 4$

points Signing the informed consent form

**Exclusion criteria:**  
Patients in shock state Acute kidney injury Chronic kidney injury History of hemorrhage in past one month Invasive surgical procedures which needs to enoxaparin discontinuation Pregnancy Lactation Thrombophilia Antithrombin deficiency Previous history of venous thrombosis Body mass index more than 35 kg/m2 Platelet less than 50000 cells/uL

**Age**  
From **18 years** old to **65 years** old

**Gender**  
Both

**Phase**  
2-3

**Groups that have been masked**  
*No information*

**Sample size**  
Target sample size: **60**  
Actual sample size reached: **60**

**Randomization (investigator's opinion)**  
Randomized

**Randomization description**  
In this study, block randomization method was used and 15 blocks which consist of 4 patient in each block, will be generated through online randomization website. In each block, two patients allocated to group one (Enoxaparin at dose of 40 mg/day) and two patients allocated to group two (Enoxaparin at dose of 1 mg/kg/day). Then, sampling will be done through individual sampling method.

**Blinding (investigator's opinion)**  
Not blinded

**Blinding description**

**Placebo**  
Not used

**Assignment**  
Parallel

**Other design features**

**Secondary Ids**  
empty

**Ethics committees**

**1**

**Ethics committee**

**Name of ethics committee**  
Vice-Chancellor in Research Affairs - Shahid Beheshti University of Medical Sciences

**Street address**  
3 rd floor, School of Medicine, Evin St, Shahid Chamran Highway

**City**  
Tehran

**Province**  
Tehran

**Postal code**  
1983963113

**Approval date**  
2018-07-02, 1397/04/11

**Ethics committee reference number**  
IR.SBMU.PHARMACY.REC.1397.069

## Health conditions studied

### 1

#### **Description of health condition studied**

Deep vein thrombosi

#### **ICD-10 code**

I82

#### **ICD-10 code description**

Other venous embolism and thrombosis

## Primary outcomes

### 1

#### **Description**

The activity level of anti factor Xa

#### **Timepoint**

Three hours after third doses

#### **Method of measurement**

Chromogenic assay

## Secondary outcomes

### 1

#### **Description**

occurance rate of deep vein thrombosis

#### **Timepoint**

Daily

#### **Method of measurement**

Clinical examination and sonography is necessary cases

### 2

#### **Description**

Occurrence rate of adverse drug reactions

#### **Timepoint**

Daily

#### **Method of measurement**

Observation

## Intervention groups

### 1

#### **Description**

Control group: Patients receive pre-filled syringes of enoxaparin (manufactured by Alborz Daroo company) at dose of 40 mg/day through subcutaneous route.

#### **Category**

Prevention

### 2

#### **Description**

Intervention group: Patients receive pre-filled syringes of enoxaparin (manufactured by Alborz Daroo company) at

dose of 1 mg/kg/day through subcutaneous route.

**Category**

Prevention

**Recruitment centers**

**1**

**Recruitment center**

**Name of recruitment center**

Loghman Hakim Hospital

**Full name of responsible person**

Zahra Sahraei

**Street address**

Loghman Hakim Hospital, Kamali St, Makhsoos St

**City**

Tehran

**Province**

Tehran

**Postal code**

1333635445

**Phone**

+98 21 5541 9005

**Email**

zahra.sahraei@yahoo.com

**Sponsors / Funding sources**

**1**

**Sponsor**

**Name of organization / entity**

Shahid Beheshti University of Medical Sciences

**Full name of responsible person**

Afshin Zarghi

**Street address**

3 rd floor, School of Medicine, Evin St, Shahid Chamran Highway

**City**

Tehran

**Province**

Tehran

**Postal code**

1983963113

**Phone**

+98 21 23871

**Email**

mpd@sbmu.ac.ir

**Grant name**

**Grant code / Reference number**

**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**

Zahra Sahraei

**Position**

Assistant Professor

**Latest degree**

Ph.D.

**Other areas of specialty/work**

Medical Pharmacy

**Street address**

Loghman Hakim Hospital, Kamali St, Makhsoos St

**City**

Tehran

**Province**

Tehran

**Postal code**

1333635445

**Phone**

+98 21 5541 9005

**Email**

zahra.sahraei@yahoo.com

**Person responsible for scientific inquiries**

**Contact**

**Name of organization / entity**

Shahid Beheshti University of Medical Sciences

**Full name of responsible person**

Dr. Zahra Sahraei

**Position**

Assistant professor

**Latest degree**

Ph.D.

**Other areas of specialty/work**

Medical Pharmacy

**Street address**

Loghman Hakim Hospital, Kamali St, Makhsoos St

**City**

Tehran

**Province**

Tehran

**Postal code**

1333635445

**Phone**

+98 21 5541 9005

**Fax**

**Email**

zahra.sahraei@yahoo.com

**Web page address**

## Person responsible for updating data

### Contact

**Name of organization / entity**

Shahid Beheshti University of Medical Sciences

**Full name of responsible person**

Ali Saffaei

**Position**

Resident

**Latest degree**

Medical doctor

**Other areas of specialty/work**

Medical Pharmacy

**Street address**

Valieasr St, Niyayesh Highway, Shahid Beheshti  
University of Medical Sciences, School of Pharmacy

**City**

Tehran

**Province**

Tehran

**Postal code**

1991953381

**Phone**

+98 21 8820 0118

**Email**

alisaffaei.ss@gmail.com

## Sharing plan

**Deidentified Individual Participant Data Set (IPD)**

Yes - There is a plan to make this available

**Study Protocol**

Undecided - It is not yet known if there will be a plan to make this available

**Statistical Analysis Plan**

Undecided - It is not yet known if there will be a plan to make this available

**Informed Consent Form**

Undecided - It is not yet known if there will be a plan to make this available

**Clinical Study Report**

Undecided - It is not yet known if there will be a plan to make this available

**Analytic Code**

Undecided - It is not yet known if there will be a plan to make this available

**Data Dictionary**

Undecided - It is not yet known if there will be a plan to make this available

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

All potential data can be shared after blinding

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

Six months after results published

**To whom data/document is available**

Researchers working in academic institutions

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

For research purposes and meta analysis

**From where data/document is obtainable**

Dr. Zahra Sahraei, Loghman Hakim Hospital, Kamali St,  
Makhsos St, Tehran

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

Official letter to the researchers

**Comments**