

# Clinical Trial Protocol

## Iranian Registry of Clinical Trials

05 Jun 2026

### Evaluation of the efficacy of apixaban in the treatment of heparin-induced thrombocytopenia (HIT)

#### Protocol summary

##### Study aim

Evaluation of efficacy and safety of apixaban the treatment of heparin-induced thrombocytopenia (HIT)

##### Design

Clinical trial, without control group, sample size of 30 patients, phase 2

##### Settings and conduct

In patients admitted to the internal ward of Rasool Akram Hospital who are diagnosed with HIT by the 4T Score, heparin will be discontinued and apixaban will be started. Based on some evidences, the dose of apixaban for the treatment of HIT is 10 mg/BD for 7 days followed by 5 mg twice daily; so we will use mentioned dose in the treatment of DVT or PE and in the prevention of stroke in non-valvular AF. In prophylactic setting, we will use a dose of 2.5 mg twice a day, unless the patient experienced HIT with thrombosis that will receive apixaban in treatment dose of HIT.

##### Participants/Inclusion and exclusion criteria

Inclusion criteria: 1) Age 18 years or older 2) HIT detection based on 4T Score equal to or greater than 4  
Non-inclusion criteria: 1) Patients with active bleeding 2) Hereditary or acquired coagulation disease or bleeding disorder 3) Receiving cytochrome P-450 3A4 inhibitor or inducer compounds 4) Severe renal failure (CrCl <25 ml / min) 5) Severe liver disease 6) The patient needs surgery 7) History of unmodified cerebral aneurysm, intracranial tumor or vascular accident 8) Not participating in another study during the last 30 days 9) Pregnant and lactating women 10) Previous treatment with a non-heparin anticoagulant 11) Covid-19 Infection

##### Intervention groups

Thirty patients with heparin-induced thrombocytopenia will be screened for inclusion. Use of heparin, including non-valvular atrial fibrillation, deep vein thrombosis, pulmonary embolism, and anticoagulant prophylaxis during hospitalization will be considered.

##### Main outcome variables

Follow-up of venous and arterial thrombosis Assessment

of side effects including bleeding in various organs  
Mortality rate

#### General information

##### Reason for update

Due to updates regarding the dose of Apixaban, therapeutic intervention needs to be changed. In addition, in this study, patients with Covid-19 will not be included in the study.

##### Acronym

HIT

##### IRCT registration information

IRCT registration number: **IRCT20200325046854N1**  
Registration date: **2021-04-25, 1400/02/05**  
Registration timing: **prospective**

Last update: **2021-05-25, 1400/03/04**

Update count: **1**

##### Registration date

2021-04-25, 1400/02/05

##### Registrant information

###### Name

Maryam Farasatinasab

###### Name of organization / entity

###### Country

Iran (Islamic Republic of)

###### Phone

+98 21 4460 4800

###### Email address

maryfarasati@gmail.com

##### Recruitment status

**Recruitment complete**

##### Funding source

##### Expected recruitment start date

2021-05-22, 1400/03/01

##### Expected recruitment end date

2021-07-23, 1400/05/01  
**Actual recruitment start date**  
empty  
**Actual recruitment end date**  
empty  
**Trial completion date**  
empty  
**Scientific title**  
Evaluation of the efficacy of apixaban in the treatment of heparin-induced thrombocytopenia (HIT)

**Public title**  
Apixaban in heparin-induced thrombocytopenia  
**Purpose**  
Treatment  
**Inclusion/Exclusion criteria**  
**Inclusion criteria:**  
1) Age 18 years or older 2) HIT detection based on 4T Score equal to or above 4  
**Exclusion criteria:**  
Patients with active bleeding Patient with inherited or acquired coagulation disease or bleeding disorder Patients receiving cytochrome P-450 3A4 inhibitors or inducers Severe renal failure (CrCl <25 ml / min) Severe liver disease (including Child-Pugh B and C) The patient needs surgery History of uncorrected cerebral aneurysm, intracranial tumor or vascular accident Non-participation in research projects during the 30 days prior to the study Pregnant and lactating women Previous treatment with a non-heparin anticoagulant Covid-19 infection

**Age**  
From 18 years old

**Gender**  
Both

**Phase**  
2

**Groups that have been masked**  
No information

**Sample size**  
Target sample size: 30

**Randomization (investigator's opinion)**  
N/A

**Randomization description**

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

**Blinding description**

**Placebo**  
Not used

**Assignment**  
Single

**Other design features**

## Secondary Ids

empty

## Ethics committees

1

Ethics committee

**Name of ethics committee**  
Iran University of Medical Sciences  
**Street address**  
Shahid Hemmat Highway  
**City**  
Tehran  
**Province**  
Tehran  
**Postal code**  
1449614535  
**Approval date**  
2020-11-01, 1399/08/11  
**Ethics committee reference number**  
IR.IUMS.REC.1399.733

## Health conditions studied

1

### Description of health condition studied

Heparin-induced thrombocytopenia

### ICD-10 code

D69.6

### ICD-10 code description

Thrombocytopenia, unspecified

## Primary outcomes

1

### Description

Follow-up of arterial / venous thrombosis after receiving apixaban

### Timepoint

If the patient becomes symptomatic

### Method of measurement

Doppler ultrasound

## Secondary outcomes

1

### Description

Mortality rate

### Timepoint

Daily

### Method of measurement

Loss of vital signs and death of the patient

2

### Description

Bleeding event following the use of apixaban

### Timepoint

Daily

### Method of measurement

Based on the patient's symptoms such as petechiae

## Intervention groups

## 1

### Description

Intervention group: In patients admitted to the internal ward of Rasool Akram Hospital who are diagnosed with HIT by the 4T Score, heparin will be discontinued and apixaban will be started. Based on some evidences, the dose of apixaban for the treatment of HIT is 10 mg/BD for 7 days followed by 5 mg twice daily; so we will use mentioned dose in the treatment of DVT or PE and in the prevention of stroke in non-valvular AF. In prophylactic setting, we will use a dose of 2.5 mg twice a day, unless the patient experienced HIT with thrombosis that will receive apixaban in treatment dose of HIT.

### Category

Treatment - Surgery

## Recruitment centers

### 1

#### Recruitment center

##### Name of recruitment center

of Rasool Akram Hospital

##### Full name of responsible person

Somayyeh Nasiripour

##### Street address

Niyayesh St, Sattar Khan

##### City

Tehran

##### Province

Tehran

##### Postal code

1445613131

##### Phone

+98 21 6435 1000

##### Email

nasiripours@yahoo.com

## Sponsors / Funding sources

### 1

#### Sponsor

##### Name of organization / entity

Iran University of Medical Sciences

##### Full name of responsible person

Seyed Abbas Motevalian

##### Street address

Shahid Hemmat Highway

##### City

Tehran

##### Province

Tehran

##### Postal code

1449614535

##### Phone

+98 21 86709

##### Email

PR@iums.ac.ir

##### Grant name

##### Grant code / Reference number

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

Yes

### Title of funding source

Iran University of Medical Sciences

### Proportion provided by this source

1

### 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

Iran University of Medical Sciences

#### Full name of responsible person

Maryam Farasatinasab

#### Position

Assistant Professor of Clinical Pharmacy

#### Latest degree

Specialist

#### Other areas of specialty/work

Medical Pharmacy

#### Street address

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## Person responsible for scientific inquiries

### Contact

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Iran University of Medical Sciences

#### Full name of responsible person

Maryam Farasatinasab

#### Position

Assistant Professor of Clinical Pharmacy

#### Latest degree

Specialist

#### Other areas of specialty/work

Medical Pharmacy

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## Person responsible for updating data

### Contact

**Name of organization / entity**  
Iran University of Medical Sciences  
**Full name of responsible person**  
Somayyeh Nasiripour  
**Position**  
Assistant Professor of Clinical Pharmacy  
**Latest degree**  
Specialist  
**Other areas of specialty/work**  
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**Province**  
Tehran  
**Postal code**  
1445613131  
**Phone**  
+98 21 6435 1000  
**Email**  
nasiripours@yahoo.com

## 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

No - There is not a plan to make this available

### Informed Consent Form

No - There is not a plan to make this available

### Clinical Study Report

Yes - There is a plan to make this available

### Analytic Code

No - There is not a plan to make this available

### Data Dictionary

No - There is not a plan to make this available

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

As an article

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

08-23-2021

### To whom data/document is available

Researchers working in academic and scientific institutions

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

Eligible individuals can access patient data upon written request.

### From where data/document is obtainable

Somayyeh Nasiripour, Assistant Professor of Clinical Pharmacy, Iran University of Medical Sciences Email: nasiripours@yahoo.com Maryam Farasatinasab, Assistant Professor of Clinical Pharmacy, Iran University of Medical Sciences Email: maryfarasati@gmail.com

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

By email to responsible people

### Comments