# 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

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1445613131

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## Sponsors / Funding sources

**1**

**Sponsor**

**Name of organization / entity**
Iran University of Medical Sciences

**Full name of responsible person**
Seyed Abbas Motevalian

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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

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## Person responsible for scientific inquiries

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## Person responsible for updating data

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## 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**