

# Clinical Trial Protocol

## Iranian Registry of Clinical Trials

26 Jun 2026

### Study of bioequivalence of 5 mg Apixaban tablets in healthy volunteers after single dose oral administration

#### Protocol summary

##### Study aim

Determination of plasma concentration of 5 mg Apixaban generic product of Zist Arvand Pharmed Company and 5 mg Eliquis Reference Product

##### Design

This study is a bioequivalence phase of clinical trial with control and cross over groups which is double-blinded and randomized and will be performed on 24 healthy subjects including 12 in control group and 12 in intervention group. For randomization, simple and restricted random allocation law is used.

##### Settings and conduct

This study is carried out at Shahid Beheshti School of Pharmacy, which has been the site of many similar studies. After receiving the drug orally, blood samples are taken from the volunteers at different times and the plasma concentration of the drug is measured by LC mass. In this double-blind study, volunteers, personnel and responsible physician is unaware for the type of drug and only the person responsible is aware of the type of drug. To ensure blinding, the drugs are removed from the box and both types are similar in appearance.

##### Participants/Inclusion and exclusion criteria

Inclusion criteria: Healthy volunteers aged 18 to 50 years, Exclusion criteria: History of liver, kidney and cardiovascular diseases that can affect drug clearance from body, History of taking any medication in the last two weeks, Creatinine above 2

##### Intervention groups

Intervention group: Oral intake of 5 mg Apixaban generic product of Zist Arvand Pharmed Company with one dose and evaluation of plasma concentration up to 48 hours in the blood of healthy volunteers Control group: Oral intake of 5 mg ELIQUIS reference product of Pfizer with one dose and evaluation of plasma concentration up to 48 hours in the blood of healthy volunteers

##### Main outcome variables

Maximum plasma concentration of the drug

#### General information

##### Reason for update

##### Acronym

##### IRCT registration information

IRCT registration number: **IRCT20210201050197N4**

Registration date: **2021-12-25, 1400/10/04**

Registration timing: **retrospective**

Last update: **2021-12-25, 1400/10/04**

Update count: **0**

##### Registration date

2021-12-25, 1400/10/04

##### Registrant information

##### Name

Azadeh Haeri

##### Name of organization / entity

##### Country

Iran (Islamic Republic of)

##### Phone

+98 21 8820 0212

##### Email address

a\_haeri@sbmu.ac.ir

##### Recruitment status

**Recruitment complete**

##### Funding source

##### Expected recruitment start date

2021-11-12, 1400/08/21

##### Expected recruitment end date

2021-12-19, 1400/09/28

##### Actual recruitment start date

empty

##### Actual recruitment end date

empty

##### Trial completion date

empty

##### Scientific title

Study of bioequivalence of 5 mg Apixaban tablets in healthy volunteers after single dose oral administration

**Public title**

Bioequivalence of Apixaban

**Purpose**

Basic science

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

Healthy volunteer Age: 18-50 year

**Exclusion criteria:**

History of liver, kidney and cardiovascular diseases that can affect drug clearance from body History of taking any medication in the last two weeks Creatinine above 2

**Age**

From **18 years** old to **50 years** old

**Gender**

Both

**Phase**

Bioequivalence

**Groups that have been masked**

- Participant
- Care provider
- Investigator
- Outcome assessor
- Data analyser

**Sample size**

Target sample size: **24**

**Randomization (investigator's opinion)**

Randomized

**Randomization description**

In order to randomize in this study, simple and restricted random allocation rule will be used. This method represents a large block for the total sample size, meaning that the balance in the number of people assigned to each group will be achieved at the end. For this purpose, first, 24 candidates who meet the inclusion criteria will be selected. Then, 12 lotteries for the intervention group and 12 lotteries for the control group will be placed inside a lottery container. Then, randomly, each of these 24 individuals will take a lottery out of the container without replacement and deliver the lottery to the project officer and the allocation of the group to the individual will be determined (the person, physician and nurse responsible are not aware of the allocation of the group to the individual). In the second phase of the study, the person in the control group will be transferred to the intervention group and vice versa.

**Blinding (investigator's opinion)**

Double blinded

**Blinding description**

Volunteers and study physician are not aware of what products they have received at any time. Since the drug is removed from its box and blister and give to the volunteers, they will not know the type of medicine. The new drug are similar to the reference drug in terms of color, smell, flavor and consistency and all the apparent properties so that participants do not know the type of drug.

**Placebo**

Not used

**Assignment**

Crossover

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

empty

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

School of Pharmacy Nursing and Midwifery, Shahid Beheshti Medical University

**Street address**

No:2660, Faculty of Pharmacy, Shahid beheshti university of medical sciences, Nyayesh complex, Valiasr st.

**City**

Tehran

**Province**

Tehran

**Postal code**

1996835113

**Approval date**

2021-09-21, 1400/06/30

**Ethics committee reference number**

IR.SBMU.PHARMACY.REC.1400.138

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

Determination of plasma concentration of Apixaban 5 mg pharmaceutical product

**ICD-10 code**

Y44.3

**ICD-10 code description**

Anticoagulant antagonists, vitamin K and other coagulants

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

Maximum plasma concentration of the drug

**Timepoint**

Before intervention and 0.5, 1, 1.5, 2, 2.5, 3, 3.5, 4, 5, 6, 8, 10, 12, 24, 32, 48 hours after intervention

**Method of measurement**

liquid chromatography-mass (LC-MS) device

**Secondary outcomes**

empty

## Intervention groups

### 1

#### Description

Intervention group: In this group, 12 volunteers receive a 5 mg Apixaban tablet made by Bio Arvand Pharmed Company. After 48 hours, blood samples will be taken from the volunteers and plasma concentration of the drug will be measured by liquid chromatography. Each time, 5 cc blood samples are taken from volunteers. Then these 12 volunteers will enter the control group after one week.

#### Category

Other

### 2

#### Description

Control group: In this group, 12 volunteers receive 5 mg Eliquis tablet made by Pfizer company. After 48 hours, blood samples will be taken from the volunteers and plasma concentration of the drug will be measured by liquid chromatography. Each time, 5 cc blood samples are taken from volunteers. Then these 12 volunteers will enter the intervention group after one week.

#### Category

Other

## Recruitment centers

### 1

#### Recruitment center

##### Name of recruitment center

School of Pharmacy, Shahid Beheshti University of Medical Sciences

##### Full name of responsible person

Azadeh Haeri

##### Street address

No:2660, Faculty of Pharmacy, Shahid beheshti university of medical sciences, Nyayesh complex, Valiasr st.

##### City

Tehran

##### Province

Tehran

##### Postal code

1996835113

##### Phone

+98 21 8820 0212

##### Email

a\_haeri@sbmu.ac.ir

## Sponsors / Funding sources

### 1

#### Sponsor

##### Name of organization / entity

Shahid Beheshti University of Medical Sciences

##### Full name of responsible person

Afshin Zarghi

##### Street address

5th Floor, Bldg No.2 SBMU, Arabi abbas Ave, Yaman Blvd, Chamran Blvd

##### City

Tehran

##### Province

Tehran

##### Postal code

19839-63113

##### Phone

+98 21 2243 9781

##### Email

Mpajouhesh@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

Azadeh Haeri

##### Position

Associate professor

##### Latest degree

Ph.D.

##### Other areas of specialty/work

Medical Pharmacy

##### Street address

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## Person responsible for scientific inquiries

### Contact

**Name of organization / entity**

Shahid Beheshti University of Medical Sciences

**Full name of responsible person**

Azadeh Haeri

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Associate professor

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Ph.D.

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### Contact

**Name of organization / entity**

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## Sharing plan

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

Undecided - It is not yet known if there will be 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**

No - There is not a plan to make this available

**Clinical Study Report**

No - There is not 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