

Clinical Trial Protocol

Iranian Registry of Clinical Trials

16 Sep 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		Assignment	Crossover
Public title		Other design features	
Bioequivalence of Apixaban		Secondary Ids	
Purpose		empty	
Basic science		Ethics committees	
Inclusion/Exclusion criteria		1	
Inclusion criteria:		Ethics committee	
Healthy volunteer Age: 18-50 year		Name of ethics committee	
Exclusion criteria:		School of Pharmacy Nursing and Midwifery, Shahid Beheshti Medical University	
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		Street address	
Age		No:2660, Faculty of Pharmacy, Shahid beheshti university of medical sciences, Nyayesh complex, Valiasr st.	
From 18 years old to 50 years old		City	
Gender		Tehran	
Both		Province	
Phase		Tehran	
Bioequivalence		Postal code	
Groups that have been masked		1996835113	
• Participant • Care provider • Investigator • Outcome assessor • Data analyser		Approval date	
Sample size		2021-09-21, 1400/06/30	
Target sample size: 24		Ethics committee reference number	
Randomization (investigator's opinion)		IR.SBMU.PHARMACY.REC.1400.138	
Randomized		Health conditions studied	
Randomization description		1	
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.		Description of health condition studied	
Blinding (investigator's opinion)		Determination of plasma concentration of Apixaban 5 mg pharmaceutical product	
Double blinded		ICD-10 code	
Blinding description		Y44.3	
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.		ICD-10 code description	
Placebo		Anticoagulant antagonists, vitamin K and other coagulants	
Not used		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

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19839-63113

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+98 21 2243 9781

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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

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

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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

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Person responsible for updating data

Contact

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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