

# Clinical Trial Protocol

## Iranian Registry of Clinical Trials

26 Jun 2026

### Comparative bioequivalence study of Apixaban 5 mg Tablet of Actoverco. and Eliquis of Pfizer as reference in 24 healthy male under fasting.

#### Protocol summary

##### Study aim

This study will be performed to compare the pharmacokinetics and in vivo parameters of Apixaban 5 mg Tablet formulation as a test product with Eliquis 5 mg Tablet formulation as a reference product and to evaluate the bioequivalence of these two formulations.

##### Design

Non-blinded, randomized, crossover in vivo bioequivalence study in 24 healthy males under fasting conditions. Block randomization for a treatment sequence of Test/Reference or Reference/Test will be used.

##### Settings and conduct

In each period, volunteers will receive a single dose intervention (1 or 2) in the Farabi Clinic (Eslamshahr, Tehran). 16 blood samples were collected during 48 hours post intervention. A 7-day washout interval separated to study periods.

##### Participants/Inclusion and exclusion criteria

Inclusion Criteria: Healthy subjects (male) with 20 - 45 years of age and Body Mass Index (BMI) within 15% of the accepted values between 18.5 and 30, calculated as kg/m<sup>2</sup>. Subjects with no significant diseases or clinically significant abnormal findings during screening, medical history, clinical examination, and laboratory evaluations; Exclusion Criteria: Subjects with known allergies to the products tested Creatinine Clearance (CrCl) of more than 50

##### Intervention groups

Intervention group 1: Apixaban 5 mg Tablet, produced by Actoverco. is the test product. In each period, 12 of 24 subjects will be given a single oral dose of this product. Intervention group 2: Eliquis 5 mg Tablet, produced by Pfizer is the reference product. In each period, 12 of 24 subjects will be given a single oral dose of this product.

##### Main outcome variables

Peak Plasma Concentration

#### General information

##### Reason for update

##### Acronym

##### IRCT registration information

IRCT registration number: **IRCT20180620040164N37**

Registration date: **2022-11-28, 1401/09/07**

Registration timing: **prospective**

Last update: **2022-11-28, 1401/09/07**

Update count: **0**

##### Registration date

2022-11-28, 1401/09/07

##### Registrant information

##### Name

Behzad Montaha Sangari

##### Name of organization / entity

Noor research and educational institute (Tavan)

##### Country

Iran (Islamic Republic of)

##### Phone

+98 21 6600 7026

##### Email address

info@tavaninstitute.ir

##### Recruitment status

**Recruitment complete**

##### Funding source

##### Expected recruitment start date

2022-12-09, 1401/09/18

##### Expected recruitment end date

2022-12-23, 1401/10/02

##### Actual recruitment start date

empty

##### Actual recruitment end date

empty

##### Trial completion date

empty

**Scientific title**

Comparative bioequivalence study of Apixaban 5 mg Tablet of Actoverco. and Eliquis of Pfizer as reference in 24 healthy male under fasting.

**Public title**

Comparative in vivo evaluation of 2 Apixaban 5 mg Tablet formulations.

**Purpose**

Treatment

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

Healthy subjects (male) between 20 – 45 years of age and Body Mass Index (BMI) within 15% of the normal range according to the accepted normal values between 18.5 and 30 (inclusive), calculated as kg/m<sup>2</sup>. Subjects with no significant diseases or clinically significant abnormal findings during screening, medical history, clinical examination, and laboratory evaluations Subjects with normal vital signs PT (prothrombin time) and aPTT (activated partial prothrombin time) within the normal range Subjects who agree with a patient consent form

**Exclusion criteria:**

Subjects with known allergies to the products tested  
Creatinine Clearance (CrCl) of more than 50  
Consumption of caffeine-containing products from 24 hours before dosing till 24 hours after its administration  
Any clinically significant illness during the 4 weeks prior to the first study drug administration  
Hypotension (systolic blood pressure  $\leq$ 100 mmHg or diastolic blood pressure  $\leq$ 65 mmHg) or hypertension (systolic blood pressure  $\geq$ 150mmHg or diastolic blood pressure  $\geq$ 100 mmHg)  
Smoking more than 10 cigarettes per day and could not tolerate cigarette cessation during each clinical period  
Recent use of concomitant medication (prescription or over-the-counter) that could increase the risk of bleeding, or influence apixaban pharmacokinetics  
History of alcohol or drug abuse  
Heavy drinkers of caffeine, grapefruit juice, or caffeinated drinks or who are on a special diet (such as vegetarians) or do exertional physical activity  
A history of difficulty with donating blood or donation of more than 500 ml blood within 7 days prior to the start of the study

**Age**

From **20 years** old to **45 years** old

**Gender**

Male

**Phase**

Bioequivalence

**Groups that have been masked**

*No information*

**Sample size**

Target sample size: **24**

**Randomization (investigator's opinion)**

Randomized

**Randomization description**

The randomization schedule will be generated with <https://www.sealedenvelope.com/simple-randomiser/v1/li> sts. A 2\*2 block randomization list is created. We have 12 blocks and within each two volunteer numbers (allocated after screening) for all 24 volunteers. According to this list, a treatment sequence of

Test/Reference or Reference/Test will be given to each volunteer.

**Blinding (investigator's opinion)**

Not blinded

**Blinding description****Placebo**

Not used

**Assignment**

Crossover

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

empty

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

Ethics Committee, School of Pharmacy, Nursing & Midwifery - Shahid Beheshti University of medical sciences

**Street address**

Niayesh Highway, Valiasr Ave, Tehran, Iran

**City**

Tehran

**Province**

Tehran

**Postal code**

1996835113

**Approval date**

2022-10-25, 1401/08/03

**Ethics committee reference number**

IR.SBMU.PHARMACY.REC.1401.127

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

other thrombophilia

**ICD-10 code**

D68.6

**ICD-10 code description**

Other thrombophilia

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

Peak Plasma Concentration (C<sub>max</sub>)

**Timepoint**

16 blood samples will be withdrawn pre-dose and at 0.5, 1, 1.5, 2, 2.5, 3, 3.5, 4, 5, 6, 8, 9, 10, 12, 24 and 48 hours after intervention.

**Method of measurement**

Using non-compartmental model of Win-Nonlin Professional software version 3.2.A (Pharsight Corporation, USA)

## Secondary outcomes

### 1

#### Description

AUC (Area Under the Concentration-Time Curve)

#### Timepoint

16 blood samples will be withdrawn pre-dose and at 0.5, 1, 1.5, 2, 2.5, 3, 3.5, 4, 5, 6, 8, 9, 10, 12, 24 and 48 hours after intervention.

#### Method of measurement

Using non-compartmental model of Win-Nonlin Professional software version 3.2.A (Pharsight Corporation, USA)

## Intervention groups

### 1

#### Description

Intervention group 1: Apixaban 5 mg Tablet, produced by Actoverco. is the test product. In each period, 12 of 24 subjects will be given single oral dose of this product. After 7-day wash-out period the intervention 2 will be given to these subjects.

#### Category

Treatment - Drugs

### 2

#### Description

Intervention group 2: Eliquis 5 mg tablet, produced by Pfizer is the reference product. In each period, 12 of 24 subjects will be given single oral dose of this product. After 7-day wash-out period the intervention 1 will be given to these subjects.

#### Category

Treatment - Drugs

## Recruitment centers

### 1

#### Recruitment center

##### Name of recruitment center

Hakim Farabi Clinic

##### Full name of responsible person

Ebrahim Siahpoosh

##### Street address

No. 57, Shemshad alley, in front of Sallor town

##### City

Tehran

##### Province

Tehran

##### Postal code

4635314588

##### Phone

+98 21 9253 5647

##### Email

partochem@gmail.com

## Sponsors / Funding sources

### 1

#### Sponsor

##### Name of organization / entity

Actover Pharmaceutical Co.

##### Full name of responsible person

Dr. Ramin Daneshmir

##### Street address

No. 58, 8th St., Gisha

##### City

Tehran

##### Province

Tehran

##### Postal code

1446863914

##### Phone

+98 21 4162 7000

##### Email

info@actoverco.com

#### Grant name

#### Grant code / Reference number

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

Yes

#### Title of funding source

Actover Pharmaceutical Co.

#### Proportion provided by this source

100

#### Public or private sector

Private

#### Domestic or foreign origin

Domestic

#### Category of foreign source of funding

empty

#### Country of origin

#### Type of organization providing the funding

Industry

## Person responsible for general inquiries

#### Contact

##### Name of organization / entity

Noor Research & Development Institute

##### Full name of responsible person

Ali Aghaei

##### Position

Master

##### Latest degree

Master

##### Other areas of specialty/work

Pharmacy

##### Street address

Sharif innovation station, North Habibollah Street, Hosseini Square, Teymoury Street, Tarasht.

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##### Province

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##### Postal code

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## Person responsible for scientific inquiries

### Contact

**Name of organization / entity**  
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Principal investigator  
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Ph.D.  
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Medical Pharmacy  
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## Person responsible for updating data

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Tehran  
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**Postal code**  
1459926609  
**Phone**  
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**Email**  
partochem@gmail.com

## 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**  
No - There is not 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**  
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