Clinical Trial Protocol
Iranian Registry of Clinical Trials

16 Sep 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 invivo 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/m2. 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)

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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/m2. 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 ≤100 mmHg or diastolic blood pressure ≤65 mmHg) or hypertension (systolic blood pressure ≥150mmHg or diastolic blood pressure ≥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/lists. 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 (Cmax)
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
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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
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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
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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
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