Clinical Trial Protocol
Iranian Registry of Clinical Trials

16 Sep 2026

Bioequivalence study of Rivaroxaban 20 mg tablet (Tehran Darou) versus Xalerto® 20 mg (Bayer) Tablet after single oral dosing in healthy volunteers

Protocol summary

Study aim

Bioequivalence study of Rivaroxaban 20 mg tablet (Tehran Darou) versus Xalelto® 20 mg (Bayer) Tablet after single oral dosing in healthy volunteers

Design

Bioequivalence study, with control group, double-blind, randomized, on 24 volunteers, from each volunteer 17 blood samples were taken. Excel software rand function is used for randomization.

Settings and conduct

The subject of this biopharmaceutical and pharmacokinetic study is the location of Tehran Shimi Company located in Tehran. The study was blinded to the study participants by removing the drugs from the original package and placing the test and reference drugs in the same package, and the participants were not aware of the type of drug they were taking. The crossover design is such that Iranian medicine will be prescribed to the first group in the first week and to the second group in the second week. Brand medicine will be prescribed to the second group in the first week and to the first group in the second week.

Participants/Inclusion and exclusion criteria

Inclusion criteria: general health (liver, heart and kidneys), body mass index (18-28), informed consent, age (50-18) Exclusion criteria: smoking, history of cardiovascular disease, history of liver disease and Renal, alcohol and drug addiction, history of allergy to Rivaroxaban

Intervention groups

Intervention group: Receives one tablet of test drug (Rivaroxaban 20 mg tablet Tehran Darou Pharmaceutical Company). Control group: Receives one reference medicine tablet (Xarelto® 20 mg Bayer Pharmaceutical Company). In both groups after receiving the Tablet Blood samples were taken from the volunteers for 24 hours at the mentioned times after drug administration and the drug concentration in plasma samples was measured by liquid chromatography with UV detector

Main outcome variables

Determination of blood concentration profile parity of brand drug with generics

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20220111053692N4**
Registration date: **2022-06-26, 1401/04/05**
Registration timing: **prospective**

Last update: **2022-06-26, 1401/04/05**
Update count: **0**

Registration date

2022-06-26, 1401/04/05

Registrant information

Name

Bardia Jamali

Name of organization / entity

Country

Iran (Islamic Republic of)

Phone

+98 21 8897 4707

Email address

info@tampouya.com

Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2022-07-01, 1401/04/10

Expected recruitment end date

2022-09-21, 1401/06/30

Actual recruitment start date
empty
Actual recruitment end date
empty
Trial completion date
empty

Scientific title
Bioequivalence study of Rivaroxaban 20 mg tablet (Tehran Darou) versus Xalerto® 20 mg (Bayer) Tablet after single oral dosing in healthy volunteers

Public title
Bioequivalence study of Rivaroxaban 20 mg tablet
Purpose
Other
Inclusion/Exclusion criteria
Inclusion criteria:
18 to 55 years old Weight in range of 10 % proper body weight All volunteers should be in a good health condition on the basis of medical history, physical examination, routine blood test. and possessing negative test for hepatitis B surface antigen (HBs-Ag), antihepatitis-C antibody (anti-HCV), and anti-HIV. just man
Exclusion criteria:
Volunteers with hypersensitivity to Rivaroxaban were excluded. those with known history of drug abuse. alcohol consumer or cigarette smokers. Taking medications that have drug interactions with Metformin until one month before studying. disinclination to take the test Blood donation or blood loss of more than 200 ml in the past month
Age
From **18 years** old to **55 years** old
Gender
Male

Phase
Bioequivalence
Groups that have been masked

- Participant
- Care provider

Sample size
Target sample size: **24**
Randomization (investigator's opinion)
Randomized
Randomization description
A group of 24 people is then selected as the sample size using Excel software in a balanced way, one of the AB or BA sequences is randomly assigned to each candidate. They are then randomly divided into two groups of 12 and given to one group of test tablets and to the other group of reference tablets.
Blinding (investigator's opinion)
Double blinded
Blinding description
This study is a Double-blind (participant) clinical trial. Rivaroxaban and Xarelto tablets are removed from the package by the administrator and placed in similar and coded cans.
Placebo
Not used
Assignment
Crossover
Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee
Name of ethics committee
Research Ethics Committees of The Institute of Pharmaceutical Sciences -Tehran University of Medical
Street address
Research Institute of Pharmaceutical Sciences, second floor of the old building, Faculty of Pharmacy, Enqelab Square, 16 Azar St.
City
Tehran
Province
Tehran
Postal code
1417613151
Approval date
2021-09-15, 1400/06/24
Ethics committee reference number
IR.TUMS.TIPS.REC.1400.127

Health conditions studied

1

Description of health condition studied
Bioequivalence study of Rivaroxaban 20 mg tablet (Tehran Darou) versus Xalerto® 20 mg (Bayer) Tablet after single oral dosing in healthy volunteers
ICD-10 code
ICD-10 code description

Primary outcomes

1

Description
Drug concentration in plasma samples
Timepoint
In times 0، 0.5، 1، 1.5، 2، 2.5، 3، 4، 5، 6، 7، 8، 10، 24، 30 Hours after the start of the intervention
Method of measurement
chromatography

Secondary outcomes

empty

Intervention groups

1

Description
Intervention group: Intervention group: Receives one tablet of test drug (Rivaroxaban 20 mg tablet Tehran Darou Pharmaceutical Company). Blood samples were taken from the volunteers for 24 hours at the mentioned times after drug administration and the drug concentration in plasma samples was measured by liquid chromatography with UV detector.

Category
Other

2

Description
Control group: Receives one reference medicine tablet (Xarelto® 20 mg Bayer Pharmaceutical Company). Blood samples were taken from the volunteers for 24 hours at the mentioned times after drug administration and the drug concentration in plasma samples was measured by liquid chromatography with UV detector

Category
Other

Recruitment centers

1

Recruitment center

Name of recruitment center
Tehran Chemie Pharmaceuticals Company

Full name of responsible person
Bardia Jamali

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Navard Ave, 17 Shahrivar St, 5th Km of Fat`h Highway,

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Sponsors / Funding sources

1

Sponsor

Name of organization / entity
tehran darou Pharmaceutical Company

Full name of responsible person
Dr. Massoud Abdul Karimi

Street address
9th .Km of Karaj Makhsous Rd. Tehran

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Web page address
http://www.tehrandarou.com

Grant name

Grant code / Reference number

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

Title of funding source
tehran darou Pharmaceutical Company

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
Persons

Person responsible for general inquiries

Contact

Name of organization / entity
Tam Pouya Consulting & Research Company

Full name of responsible person
Bardia Jamali

Position
manager

Latest degree
Ph.D.

Other areas of specialty/work
Medical Pharmacy

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Person responsible for scientific inquiries

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Position
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Latest degree
Ph.D.

Other areas of specialty/work
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Person responsible for updating data

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Sharing plan

Deidentified Individual Participant Data Set (IPD)
No - There is not a plan to make this available

Justification/reason for indecision/not sharing IPD
No more information

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