

Clinical Trial Protocol

Iranian Registry of Clinical Trials

29 Jun 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 Xalerto® 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 (Xalerto® 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

Street address

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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1399615851

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Email

info@tehrandarou.com

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

Contact

Name of organization / entity

Tam Pouya Consulting & Research Company

Full name of responsible person

Bardia Jamali

Position

manager

Latest degree

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Other areas of specialty/work

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Person responsible for updating data

Contact

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Full name of responsible person

Motahareh Moafi

Position

Office worker

Latest degree

Bachelor

Other areas of specialty/work

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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