Clinical Trial Protocol
Iranian Registry of Clinical Trials

30 Jun 2026

A cross over bioequivalence study of Rivaroxaban 20 mg tab compared to Xarelto 20 mg tab manufactured by Bayer 24 healthy volunteers under fasting condition

Protocol summary

Study aim

Comparison of bioavailability of rivaroxaban after single dose of 20 mg tablet made by Pars Daroo and Bayer

Design

The study is cross-over. 24 healthy volunteers randomly receive one of the two test or reference drugs in each phase of the study, a total of 13 blood samples is received from the individual

Settings and conduct

On the sampling day, after 10 hours fasting, the volunteers will take a single dose of 20 mg test or reference drug with 240 ml of water, and blood saomples are taken at times of 0.5, 1, 1.5, 2, 2.5, 3, 4, 5, 6, 8, 10 24 and 30 hours after drug administration, then samples are transferred to -70 freezer after plasma separation finally the plasma drug concentration is determined according to LCMSMS method. After a wash out period of week in the second phase, the candidates who received the test drug in the first phase will receive the reference sample, and the people who had previously received the reference sample will receive the test sample in the second phase.

Participants/Inclusion and exclusion criteria

Healthy male volunteers without a history of heart, liver, kidney, lung, coagulation disorders and people who have not taken any medication since one month before the study also have systolic blood pressure above 13 and below 10 and diastolic blood pressure below 6 and above From 85 mm Hg, heart rate not more than 90 or less than 60 beats per minute,

Intervention groups

Blood concentration of rivaroxaban of Pars Darou is compared to Bayer product

Main outcome variables

Plasma concentration of test and reference drug

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20220209053979N1**
Registration date: **2022-06-24, 1401/04/03**
Registration timing: **prospective**

Last update: **2022-06-24, 1401/04/03**
Update count: **0**

Registration date

2022-06-24, 1401/04/03

Registrant information

Name

Roya Talari

Name of organization / entity

Country

Iran (Islamic Republic of)

Phone

+98 21 8880 0892

Email address

talari_r@yahoo.com

Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2022-07-21, 1401/04/30

Expected recruitment end date

2022-07-29, 1401/05/07

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title
A cross over bioequivalence study of Rivaroxaban 20 mg tab compared to Xarelto 20 mg tab manufactured by Bayer 24 healthy volunteers under fasting condition

Public title
A bioequivalence study of Rivaroxaban 20 mg tab compared to Xarelto 20 mg tab manufactured by Bayer in 24 healthy volunteers under fasting condition

Purpose
Basic scienece

Inclusion/Exclusion criteria

Inclusion criteria:
Have no history of heart, liver, kidney, lung, coagulation disorders They have not taken any medication at least one month before starting the study

Exclusion criteria:
Systolic blood pressure above 13 and below 10 and diastolic blood pressure below 6 and above 85 mm Hg heart rate more than 90 or less than 60 beats per minute

Age
From **18 years** old to **55 years** old

Gender
Both

Phase
Bioequivalence

Groups that have been masked

- Participant
- Data analyser

Sample size
Target sample size: **24**
More than 1 sample in each individual
Number of samples in each individual: **13**
6 ml blood samples

Randomization (investigator's opinion)
Randomized

Randomization description
Each volunteer is assigned a code. In this way, half of the codes in the first phase of sampling receive the test drug and half of them receive reference drug, and in the second phase of the study, vice versa. The group that took the test drug in the first phase will take the reference drug in the second phase and the group that received the reference drug in the first phase will take the test drug.

Blinding (investigator's opinion)
Double blinded

Blinding description
The drug (test or reference drug) is removed from the original packaging the day before the study and packaged in small disposable containers. Therefore, it is not in the original packaging, none of the volunteer nor the prescriber know which drug is being delivered.

Placebo
Not used

Assignment
Crossover

Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee
Research Institute of Pharmaceutical Sciences, Tehran University of Medical Sciences

Street address
16 Azar St., Enghelab Sq., Tehran, Iran

City
Tehran

Province
Tehran

Postal code
۱۴۱۹۷۳۳۱۴۱

Approval date
2022-06-12, 1401/03/22

Ethics committee reference number
IR.TUMS.TIPS.REC.1401.020

Health conditions studied

1

Description of health condition studied
Investigation of bioequivalence of Rivaroxaban tablets manufactured by Pars Daroo company in comparison to the xarelto made by Bayer company

ICD-10 code

ICD-10 code description

Primary outcomes

1

Description
Plasma concentration of the drug obtained from rivaroxaban tablets made by Pars Darou Company and Bayer Company

Timepoint
0.5, 1, 1.5, 2, 2.5, 3, 4, 5, 6, 8, 10, 24, 32 hour

Method of measurement
LCMSMS

Secondary outcomes

empty

Intervention groups

1

Description
Intervention group: Plasma concentration of test and reference drug, and area below concentration-time curve of test and reference drug

Category

Other

Recruitment centers

1

Recruitment center

Name of recruitment center
Kharazmi Plasma Center of Islamshahr

Full name of responsible person
Sara Solgi

Street address
No. 13.First Shahamat Alley,Ali Ibn Abitaleb Street, Namaz Square, Islamshahr,

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Tehran

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3313679886

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Email
Info@kpcir.com

Web page address

Sponsors / Funding sources

1

Sponsor

Name of organization / entity
Pars Darou

Full name of responsible person
Fatemeh Zadsaleh

Street address
No. 13, 144 East St., The first square of Tehran Pars,

City
Tehran

Province
Tehran

Postal code
1654713691

Phone
+98 21 7770 4061

Fax
+98 21 7787 7700

Email
info@parsdarou.com

Grant name

Grant code / Reference number

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

Title of funding source
Pars Darou

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
Other

Person responsible for general inquiries

Contact

Name of organization / entity
Kharazmi Plasma Center

Full name of responsible person
Roya Talari

Position
executor of plan

Latest degree
Ph.D.

Other areas of specialty/work
Medical Pharmacy

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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
Pars Daroo factory may not allow us to publish data.
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
Undecided - It is not yet known if there will be 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