# Clinical Trial Protocol
# Iranian Registry of Clinical Trials

30 Jun 2026

## In- Vivo Bioequivalence study of Rivaroxaban tablet 10 and 20mg Jaber-ebne Hayyan Pharma with brand drug (XARELTO® 10 and 20mg Bayer, Germany) in Iranian healthy volunteers.

## Protocol summary

**Study aim**

In- Vivo Bioequivalence study of Rivaroxaban tablet 10 and 20mg Jaber-ebne Hayyan Pharma with brand drug (XARELTO® 10 and 20mg Bayer, Germany) in Iranian healthy volunteers.

**Design**

Single dose, randomized, two sequences, two period crossover with a washout period.

**Settings and conduct**

This study will be conducted in one-way, cross-over and fasting, and on two sets of healthy volunteers. The study will be conducted in two periods of 72 hours.The interval between these two periods, which is called the wash-out time, is determined by the half-life of the drug plasma, which according to scientific sources should be at least 5 to 7 half-life of the drug in the case of the drug under study. The plan will take a week to clean up the drug, given the biological half-life of the drugs in the drug form.In the first round, candidates are divided into two groups, and the first group receives a test tablet and the second group receives a similar tablet. Blood samples will taken by the volunteer by the technician immediately after taking the drug, and the preparation steps of the samples, including plasma separation and drug extraction, are performed to analyze the amount of drug on them.

**Participants/Inclusion and exclusion criteria**

24 participants will be selected from non-smoking, not pregnant people with no history of heart, kidney and liver disease or dis functions with both sex (male&female). The ages and BMIs of participant should be in the range of 18-60 and 18-28 respectively

**Intervention groups**

Intervention group Single dose Rivaroxaban tablet 10 and 20mg Jaber-ebne Hayyan Pharma Company with brand drugs (Xarelto® 10 & 20mg Bayer, Germany )

**Main outcome variables**

Determination of blood drug concentration.

## General information

**Reason for update**

**Acronym**

**IRCT registration information**

IRCT registration number: **IRCT20200105046010N27**
Registration date: **2021-04-05, 1400/01/16**
Registration timing: **prospective**

Last update: **2021-04-05, 1400/01/16**
Update count: **0**

**Registration date**

2021-04-05, 1400/01/16

**Registrant information**

**Name**

Javad Shokri

**Name of organization / entity**

**Country**

Iran (Islamic Republic of)

**Phone**

+98 41 3661 4125

**Email address**

shokri.j@gmail.com

**Recruitment status**

**Recruitment complete**

**Funding source**

**Expected recruitment start date**

2021-06-04, 1400/03/14

**Expected recruitment end date**

2021-12-01, 1400/09/10

**Actual recruitment start date**

empty

**Actual recruitment end date**

empty

**Trial completion date**
empty

**Scientific title**
In- Vivo Bioequivalence study of Rivaroxaban tablet 10 and 20mg Jaber-ebne Hayyan Pharma with brand drug (XARELTO® 10 and 20mg Bayer, Germany) in Iranian healthy volunteers.

**Public title**
In-vivo Bioequivalence Test of Rivaroxaban® tablet with brand drugs (Xarelto® Bayer, Germany).

**Purpose**
Treatment

**Inclusion/Exclusion criteria**
**Inclusion criteria:**
General health Body mass index(18-28) Informed consent Age(18-60)
**Exclusion criteria:**
Smoking A history of cardiovascular disease A history of liver & kidney disease Pregnancy Alcohol & Drug addiction Hypersensitivity to the drug

**Age**
From **18 years** old to **60 years** old

**Gender**
Both

**Phase**
Bioequivalence

**Groups that have been masked**
- Participant

**Sample size**
Target sample size: **24**

**Randomization (investigator's opinion)**
Randomized

**Randomization description**
Random allocation law will be used for randomization of volunteers in this study. This method represents a large block for the total sample size, which means that a balance in the number of people assigned to each group will be obtained at the end of the study. By this method, sequences 1(subjects no: 1-12) and sequences 2 (subjects no: 13-12) will be selected by using a simple paper lottery. the first and second 12 persons will be considered as sequence 1 (Group A) and sequence 2 (Group B) respectively.

**Blinding (investigator's opinion)**
Single blinded

**Blinding description**
Candidates are not aware of the test drug or brand name. In a one-blind study, information that could distort the test result is hidden from the candidates, but the person in charge of the test is aware of it. Tramadol and Tramadol are removed from their packaging by the executor and placed in similar and coded cans. Volunteers will not be informed about receiving the brand or test dosage form.

**Placebo**
Not used

**Assignment**
Crossover

**Other design features**

## Secondary Ids

empty

## Ethics committees

### 1

**Ethics committee**
**Name of ethics committee**
Ethics Committee, Tabriz University of Medical Sciences
**Street address**
Third floor of TUMS (Tabriz University of Medical Sciences) central building, Dneshgah St. Tabriz, Iran
**City**
Tabriz
**Province**
East Azarbaijan
**Postal code**
5166614766

**Approval date**
2021-03-01, 1399/12/11

**Ethics committee reference number**
IR.TBZMED.REC.1399.1115

## Health conditions studied

### 1

**Description of health condition studied**
In this study, the disease is not examined. Subject bioequivalence test and reference tablets Teriflunomide studied.

**ICD-10 code**

**ICD-10 code description**

## Primary outcomes

### 1

**Description**
Determination of blood drug concentration.

**Timepoint**
Sampling times in this study will be 0, 1, 2, 2:30, 3, 3:20, 3:40, 4, 4:20, 4: 40, 5, 6, 8, 10, 12, 24, 48, 72 hours After prescribing the tablet.

**Method of measurement**
igh Performance Liquid Chromatography with tandem mass spectroscopy detector

## Secondary outcomes

empty

## Intervention groups

### 1

**Description**
Intervention group: Intervention group received one test drug table(Rivaroxaban tablet 10 and 20mg Jaber-ebne

Hayyan Pharma). Blood samples were taken from the volunteers for 72 hours at the mentioned times after drug administration and the concentration of Rivaroxaban in blood samples was measured by liquid chromatography with mass spectroscopy detector.

**Category**

Treatment - Drugs

**2**

**Description**

Control group: Control group received one reference drug table(Rivaroxaban tablet 10 and 20mg Xarelto® Bayer, Germany). Blood samples were taken from the volunteers for 72 hours at the mentioned times after drug administration and the concentration of Rivaroxaban in blood samples was measured by liquid chromatography with mass spectroscopy detector.

**Category**

Treatment - Drugs

## Recruitment centers

**1**

**Recruitment center**

**Name of recruitment center**
Simin Baspar Teyf Gostar Company

**Full name of responsible person**
Javad Shokri

**Street address**
No.48, Ferdos Street

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Tabriz

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**Phone**
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Shokri.j@gmail.com

## Sponsors / Funding sources

**1**

**Sponsor**

**Name of organization / entity**
Jaber Ibn Hayyan Pharmaceutical Company

**Full name of responsible person**
Mahdi Madanchi

**Street address**
Km 4 Karaj road , Tehran

**City**
Tehran

**Province**
Tehran

**Postal code**
1654613111

**Phone**
+98 21 4450 3323

**Email**
HeadOffice@jaber-pharma.com

**Grant name**

**Grant code / Reference number**

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

No

**Title of funding source**

Tabriz University of Medical Sciences

**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**
Tabriz University of Medical Sciences

**Full name of responsible person**
Javad Shokri

**Position**
Professor

**Latest degree**
Ph.D.

**Other areas of specialty/work**
Medical Pharmacy

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Faculty of Pharmacy, Tabriz University of Medical Sciences.

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## Person responsible for scientific inquiries

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## Person responsible for updating data

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**Email**
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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**
These date are as secure between researcher and related industries
**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**
Yes - There is a plan to make this available
**Title and more details about the data/document**
Only protocol and methods of study are sharable
**When the data will become available and for how long**
Only protocol and methods of study are sharable.
**To whom data/document is available**
Pharmaceutical and medical sciences researchers
**Under which criteria data/document could be used**
Projects information's for any publications is not allowed.
**From where data/document is obtainable**
By email to the project manager (shokri.j@gmail.com)
**What processes are involved for a request to access data/document**
This information is confidential and is at the disposal of the project sponsor. Upon request, the information will be provided to the applicant by the contractor's email after the
**Comments**