

Clinical Trial Protocol

Iranian Registry of Clinical Trials

11 Sep 2026

Bioequivalence study of Ivabradine 7.5 mg tablet manufactured by Cobel daru versus originator brand in healthy volunteers in the fasted condition

Protocol summary

Study aim

Bioequivalence Study of Ivabradine 7.5 mg (Bradix) manufactured by Cobel daru company versus originator brand (Procora) manufactured by Sevier company

Design

Bioequivalence study, crossover, single-blinded (volunteer), 24 healthy volunteers. Simple randomization was used for randomization

Settings and conduct

The study is a single-blinded, cross-over and fasting, and on two series of healthy volunteers. The study will be done in two periods (48h). The interval between these two periods is one week. In the first round of the study, the candidates divide into two groups. the first group receives a test tablet and the second group receives a brand tablet. Blood samples are collected immediately before and after drug administration by volunteers. Then, drug extraction is done and samples are ready for analysis. The sampling and analysis steps are performed in Radin Laboratory in Tabriz.

Participants/Inclusion and exclusion criteria

Inclusion criteria: General Health (Liver, Heart, and Kidney); Body Mass Index (18-28); Informed consent; age (18-55 years old). Exclusion criteria: smoking; history of cardiovascular disease; history of liver and kidney disease; alcohol and drug addiction; history of allergy to Ivabradine.

Intervention groups

Intervention group 1: Procora 7.5mg tablet as a reference Intervention group 2: Bradix 7.5 mg as a test

Main outcome variables

Maximum drug concentration, Time to reach maximum drug concentration, Half-life of drug

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20200105046010N80**

Registration date: **2023-07-11, 1402/04/20**

Registration timing: **prospective**

Last update: **2023-07-11, 1402/04/20**

Update count: **0**

Registration date

2023-07-11, 1402/04/20

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

2023-07-23, 1402/05/01

Expected recruitment end date

2024-03-18, 1402/12/28

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Bioequivalence study of Ivabradine 7.5 mg tablet manufactured by Cobel daru versus originator brand in healthy volunteers in the fasted condition

Public title

Bioequivalence study of Ivabradine 7.5 mg tablet

Purpose

Treatment

Inclusion/Exclusion criteria**Inclusion criteria:**

General Health (Liver, Heart, and Kidney) Body Mass Index (18-28) Informed consent Age (18-55 years old)

Exclusion criteria:**Age**

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

Gender

Both

Phase

Bioequivalence

Groups that have been masked

- Participant

Sample size

Target sample size: **24**

More than 1 sample in each individual

Number of samples in each individual: **34**

Blood sample

Randomization (investigator's opinion)

Randomized

Randomization description

Each candidate is assigned a number from 1 to 24. The numbers are written on a plastic ball, poured into a container, and mixed. The balls are then removed randomly from the container and divided in 2 groups of 12 test (A) and reference (B) drug recipients, then in the second phase, groups A and B will be cross-referenced to the test and drug recipients.

Blinding (investigator's opinion)

Single blinded

Blinding description

This study is a single-blinded clinical trial (volunteers). Cobel daru's Ivabradine and Originator brand capsules 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**

Tabriz University of Medical Sciences ethics committee

Street address

3th Floor, Research and Technology Vice-Chancellor,
No 2 Central Building, Tabriz University of Medical

Sciences, Golgasht Street

City

Tabriz

Province

East Azarbaijan

Postal code

5165665931

Approval date

2023-05-29, 1402/03/08

Ethics committee reference number

IR.TBZMED.REC.1402.184

Health conditions studied**1****Description of health condition studied**

This study is performed on healthy volunteers.

ICD-10 code**ICD-10 code description****Primary outcomes****1****Description**

The concentration of the drug in blood

Timepoint

Pre-dose, 0.25, 0.5, 1, 1.25, 1.5, 2, 3, 4, 6, 7, 8, 10, 12, 24, 36 and 48 h after drug administration

Method of measurement

Liquid Chromatography Mass-Mass

Secondary outcomes**1****Description**

Time to reach maximum blood concentration

Timepoint

After intervention

Method of measurement

The time to reach the maximum drug concentration in blood is recorded

2**Description**

Extent of absorption

Timepoint

After intervention

Method of measurement

Calculation of area under curve of concentration -time

Intervention groups**1****Description**

Intervention group: single dose, one oral tablet 7.5mg(Procora) manufactured by Sevier company, as a

reference product

Category

Treatment - Drugs

2

Description

Intervention group: Single dose, one oral Bradix 7.5 mg tablet manufactured by Cobel darou company as a test product

Category

Treatment - Drugs

Recruitment centers

1

Recruitment center

Name of recruitment center

Radin Laboratory

Full name of responsible person

Javad Shokri

Street address

No.22, first floor, Moalem st., Abureihan St

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Tabriz

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5154995671

Phone

+98 914 313 5843

Email

Shokri.j@gmail.com

Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Cobel Darou Pharmaceutical Company

Full name of responsible person

Dr Sarfarzi R&D manager

Street address

No.39, corner of kambiz alley, Alvand street, Argantin Sq

City

Tehran

Province

Tehran

Postal code

13897 - 76363

Phone

+98 21 8867 1230

Fax

+98 21 8867 1240

Email

info@cobeldarou.com

Grant name

Grant code / Reference number

Is the source of funding the same sponsor

organization/entity?

Yes

Title of funding source

Cobel 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

Industry

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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Person responsible for scientific inquiries

Contact

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Person responsible for updating data

Contact

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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 data are as secure between researchers 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

No - There is not a plan to make this available