

# Clinical Trial Protocol

## Iranian Registry of Clinical Trials

10 Jun 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 daru 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  
**City**  
Tabriz  
**Province**  
East Azarbaijan  
**Postal code**  
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  
**Street address**  
No 4, 10th Ave. Boostan Street, Roshdieh, Tabriz  
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**Person responsible for scientific inquiries**

**Contact**

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Tabriz University of Medical Sciences  
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## Person responsible for updating data

### Contact

**Name of organization / entity**  
Tabriz University of Medical Sciences  
**Full name of responsible person**  
Javad Shokri  
**Position**  
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**Latest degree**  
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**Street address**  
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**City**  
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East Azarbaijan

## 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