Clinical Trial Protocol
Iranian Registry of Clinical Trials

02 Aug 2026

Pharmacokinetic assessments of Fampridine tablet 10mg extended release in comparison with brand drugs FAMPYRA

Protocol summary

Study aim

In- Vivo Bioequivalence study of Fampridine 10 mg Pharan shimi with brand drugs FAMPYRA 10mg Biogen Idec, UK

Design

Single dose of Fampridine 10 mg Pharan shimi Pharmaceutical Company.

Settings and conduct

This study will be conducted in two-way, cross-over and fasting, and on two sets of healthy volunteers. The study will be conducted in two periods of twenty-four 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

Participants/Inclusion and exclusion criteria

In this study، 24 participants of both sexes will be selected. The inclusion criteria is: general health, age between 18 to 60, body mass index between 18 to 30. Exclusion criteria is: non-pregnant and non- smokers

Intervention groups

Intervention group Single dose Fampridine 10 mg Pharan shimi Pharmaceutical Company and Control group Single dose of TRAJENTA tablet with brand drugs FAMPYRA 10mg Biogen Idec, UK.

Main outcome variables

Determination of blood drug concentration

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20200105046010N19**
Registration date: **2021-01-10, 1399/10/21**
Registration timing: **prospective**

Last update: **2021-01-10, 1399/10/21**
Update count: **0**

Registration date

2021-01-10, 1399/10/21

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

2021-03-05, 1399/12/15

Expected recruitment end date

2021-07-27, 1400/05/05

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Pharmacokinetic assessments of Fampridine tablet 10mg extended release in comparison with brand drugs FAMPYRA

Public title

In-vivo Bioequivalence Test Fampridine tablet with brand drug FAMPYRA Made by Biogen Idec, UK.

Purpose

Treatment

Inclusion/Exclusion criteria

Inclusion criteria:

General health Body Mass Index (BMI) between 18-28 Informed consent Age between 18-60 Both male and female

Exclusion criteria:

Smoking 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

No information

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. 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. Fampridine and FAMPYRA 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

2020-12-29, 1399/10/09

Ethics committee reference number

IR.TBZMED.REC.1399.894

Health conditions studied

1

Description of health condition studied

The aim of this study is evaluation of bioequivalence of test and reference drugs and the study will one by healthy volunteers

ICD-10 code

ICD-10 code description

Primary outcomes

1

Description

blood concentration of the drug

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 received tablet.

Method of measurement

Liquid Chromatography with tandem mass spectroscopy detector

Secondary outcomes

empty

Intervention groups

1

Description

Intervention group: Intervention group received one test drug table (Fampridine 10 mg Pharan shimi Company). Blood samples were taken from the volunteers for 72 hours at the mentioned times after drug administration and the concentration of lacosamide in blood samples was measured by liquid chromatography with mass spectroscopy detector.

Category

Treatment - Drugs

2

Description
Control group: Control group received one test drug table (FAMPYRA 10mg Biogen Idec, UK.). Blood samples were taken from the volunteers for 72 hours at the mentioned times after drug administration and the concentration of lacosamide 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
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No.48, Ferdos Street
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Shokri.j@gmail.com

Sponsors / Funding sources

1

Sponsor
Name of organization / entity
Pharan shimi Pharmaceutical Company
Full name of responsible person
sahar pedram
Street address
No. 3, Kaveh Dedend, Entezami St., Attar Square, Attar St, Tehran, Iran
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Province
Tehran
Postal code
6583117698
Phone
+98 21 5794 1000
Email
info@faranshimi.com
Grant name
Grant code / Reference number
Is the source of funding the same sponsor organization/entity?
Yes
Title of funding source
Pharan shimi 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
Tabriz University of Medical Sciences
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Javad Shokri
Position
Professor
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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
All data of the study between executor and employer will remain confidential.
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
After finishing the project and final report (about 6 months after receiving IRCT code)
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
Contact with E-mail of the main researcher
What processes are involved for a request to access data/document
Personal and academic details and the aim of the request.
Comments