

Clinical Trial Protocol

Iranian Registry of Clinical Trials

17 Sep 2026

Comparative bioequivalence study of the 10-mg Fampridine Tablets manufactured by Zahravi Pharmaceutical Company

Protocol summary

Study aim

Demonstration of bioequivalence of Fampridine 10-mg Tablet of Zahravi Pharmaceutical Company with Fampyra® Tablet manufactured by Biogen Idec company after single dose administration.

Design

Single dose, randomized and crossover bioequivalence study of Fampridine 10-mg tablet by Zahravi Co. with Fampyra® (Biogen Idec Co.) in 24 healthy male volunteers in two groups under fasting condition.

Settings and conduct

Study place and the place for Blood sample analysis are the Drug Applied Research Center affiliated to Tabriz University of Medical Science, respectively. 24 healthy male volunteers will receive each of test or reference Fampridine 10-mg Tablet in random sequence according to the randomization schedule. The interval between receiving the medicine (washout period) is 7 days, If the first sequence receives Iranian medicine, they will receive brand medicine. Blood samples will be taken from all participants before and after receiving the drug at 1, 1.5, 2, 2.5, 3, 3.5, 4, 4.5, 5, 5.5, 6, 8, 10, 12 and 24 hours after dosing.

Participants/Inclusion and exclusion criteria

Inclusion criteria: Healthy male subjects in the age range of 18-50 years and BMI (Body Mass Index) of 18.5-30. Exclusion criteria: Subjects with BP $\leq$ 90/60 mm/Hg or BP $\geq$ 140/90 mm/Hg Any evidence of impairment of renal, hepatic, cardiac, lung or gastrointestinal function or a history of TB, epilepsy, asthma, DM, psychosis or glaucoma and regular smoker.

Intervention groups

Intervention group 1: Fampridine 10-mg Tablet by Zahravi Co. is the test product. Intervention group 2: Fampyra® (Biogen Idec Co.) is the reference product. In each period, 12 of 24 subjects will be given single dose of this product.

Main outcome variables

Peak Plasma Concentration (Cmax); Area under the

concentration-time curve (AUC).

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20200407046981N23**

Registration date: **2022-01-22, 1400/11/02**

Registration timing: **prospective**

Last update: **2022-01-22, 1400/11/02**

Update count: **0**

Registration date

2022-01-22, 1400/11/02

Registrant information

Name

Fatima Molavi

Name of organization / entity

Country

Iran (Islamic Republic of)

Phone

+98 41 3336 2700

Email address

molavif@tbzmed.ac.ir

Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2022-04-08, 1401/01/19

Expected recruitment end date

2022-06-09, 1401/03/19

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty	
Scientific title	Comparative bioequivalence study of the 10-mg Fampridine Tablets manufactured by Zahravi Pharmaceutical Company
Public title	Study of absorption and elimination rate of Fampridine 10-mg tablet in comparison with Fampridine brand tablet (Fampyra®).
Purpose	Treatment
Inclusion/Exclusion criteria	
Inclusion criteria:	The weight limit of each volunteer should be between 60 and 100 kg. All volunteers must be non-smokers. They must be healthy in terms of liver, kidney, respiratory system, mental and other general health characteristics that will be assessed. Candidates who have consented to the consent form.
Exclusion criteria:	Known hypersensitivity or idiosyncratic reaction to Fampridine or any ingredients. Subjects with BP $\leq$ 90/60 mm/Hg or BP $\geq$ 140/90 mm/Hg. Regular smoker who smokes more than ten cigarettes daily. Taking any medicine during two weeks before dosing.
Age	From 18 years old to 55 years old
Gender	Male
Phase	Bioequivalence
Groups that have been masked	No information
Sample size	Target sample size: 24
Randomization (investigator's opinion)	Randomized
Randomization description	To randomly assign people in two groups, 24 cards with numbers 1 to 24 will be used in closed envelopes that are arranged irregularly. Each candidate will pick up an envelope after entering the study, and numbers 1-12 will be in group A and numbers 13-24 will be in group B. Group A will receive intervention 1 and group B will receive intervention 2, and after the first period, the interventions of the both groups will change for the second period.
Blinding (investigator's opinion)	Not blinded
Blinding description	
Placebo	Not used
Assignment	Crossover
Other design features	
Secondary Ids	empty

Ethics committees	
1	
Ethics committee	
Name of ethics committee	Ethics committee of Tabriz University of Medical Science
Street address	Third floor, central building No. 2, Golgasht street, Tabriz University of Medical Science, Tabriz, Iran
City	Tabriz
Province	East Azarbaijan
Postal code	5166614766
Approval date	2021-11-28, 1400/09/07
Ethics committee reference number	IR.TBZMED.REC.1400.812
Health conditions studied	
1	
Description of health condition studied	Bioequivalence study
ICD-10 code	
ICD-10 code description	
Primary outcomes	
1	
Description	Peak Plasma Concentration (Cmax)
Timepoint	At 0 before dosing, 1, 1.5, 2, 2.5, 3, 3.5, 4, 4.5, 5, 5.5, 6, 8, 10, 12 and 24 hours after dosing
Method of measurement	High-performance liquid chromatography—mass spectrometry (HPLC-MS)
Secondary outcomes	
1	
Description	AUC (Area Under the Concentration-Time Curve)
Timepoint	At 0 before dosing, 1, 1.5, 2, 2.5, 3, 3.5, 4, 4.5, 5, 5.5, 6, 8, 10, 12 and 24 hours after dosing
Method of measurement	Using non-compartmental model of Win-Nonlin Professional software version 3.2.A (Pharsight Corporation, USA) or SPSS
Intervention groups	

1

Description

Intervention group 1: In this group, volunteers are given a single oral dose of Fampridine 10-mg tablet produced by Zahravi Co. (Domestic). In each period, 12 of 24 subjects will be given single oral dose of this product.

Category

Treatment - Drugs

2

Description

Intervention group 2: In this group, volunteers are given a single oral dose of Fampridine 10-mg tablet (Fampyra), produced by Biogen Idec Company (Brand). In each period, 12 of 24 subjects will be given single oral dose of this product.

Category

Treatment - Drugs

Recruitment centers

1

Recruitment center

Name of recruitment center

Drug Applied Research Center

Full name of responsible person

Dr Hamed Hamishehkar

Street address

Drug Applied Research Center, In front of Shahid Madani Hospital, Daneshgah Blvd, Tabriz, Iran

City

Tabriz

Province

East Azarbaijan

Postal code

5165665811

Phone

+98 41 3336 7914

Fax

+98 41 3336 7914

Email

hamishehkar.hamed@gmail.com

Web page address

<https://darc.tbzmed.ac.ir/>

Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Zahravi pharmaceutical company

Full name of responsible person

Hussein Eslami

Street address

No. 23, Entrance No. 2, Darupakhsh Factories,
Daropakhsh St., Karaj (Lashgari) Special Road, 18th
Corner, Tehran

City

Tehran

Province

Tehran

Postal code

1397116396

Phone

+98 21 4499 1893

Fax

+98 21 4499 4315

Email

CEO@zahravipharma.com

Grant name

Grant code / Reference number

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

Yes

Title of funding source

Zahravi 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

Hamed Hamishehkar

Position

Professor

Latest degree

Ph.D.

Other areas of specialty/work

Pharmaceutics

Street address

Drug Applied Research Center, In front of Shahid Madani Hospital, Daneshgah Blvd, Tabriz, Iran

City

Tabriz

Province

East Azarbaijan

Postal code

5165665811

Phone

+98 41 3336 7914

Email

Hamishehkar.hamed@gmail.com

Person responsible for scientific inquiries

Contact

Name of organization / entity

Esfahan University of Medical Sciences

Full name of responsible person

Jaber Emami

Position

Professor

Latest degree

Ph.D.

Other areas of specialty/work

Pharmaceutics

Street address

Hezarjarib St., School of Pharmacy and
Pharmaceutical Sciences , Isfahan, Iran

City

Isfahan

Province

Isfahan

Postal code

8174673461

Phone

+98 31 3792 7111

Fax

+98 31 3668 0011

Email

Emami@pharm.mui.ac.ir

Person responsible for updating data

Contact

Name of organization / entity

Tabriz University of Medical Sciences

Full name of responsible person

Fatima Molavi

Position

Non-faculty academic specialist

Latest degree

Ph.D.

Other areas of specialty/work

Pharmaceutics

Street address

Drug Applied Research Center, In front of Shahid
Madani Hospital, Daneshgah Blvd, Tabriz, Iran

City

Tabriz

Province

East Azarbaijan

Postal code

5165665811

Phone

+98 41 3336 7914

Email

F.molavi85@gmail.com

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

There is no further information

Study Protocol

Undecided - It is not yet known if there will be a plan to
make this available

Statistical Analysis Plan

No - There is not a plan to make this available

Informed Consent Form

Undecided - It is not yet known if there will be 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

Undecided - It is not yet known if there will be a plan to
make this available

Data Dictionary

No - There is not a plan to make this available