

# 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 be 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

##### Street address

No.48, Ferdos Street

##### City

Tabriz

##### Province

East Azarbaijan

##### Postal code

5167874434

##### Phone

+98 41 3384 2724

##### Email

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

##### City

Tehran

##### 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

#### Full name of responsible person

Javad Shokri

#### Position

Professor

#### Latest degree

Ph.D.

#### Other areas of specialty/work

Medical Pharmacy

#### Street address

Faculty of Pharmacy, University of Medical Sciences,  
Daneshgah Street, Tabriz East Azerbaijan

#### City

Tabriz

#### Province

East Azarbaijan

#### Postal code

5166414766

#### Phone

+98 41 3334 8489

#### Fax

#### Email

Shokri.j@gmail.com

## Person responsible for scientific inquiries

### Contact

#### Name of organization / entity

Tabriz University of Medical Sciences

#### Full name of responsible person

Javad Shokri

#### Position

Professor

#### Latest degree

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**Person responsible for updating data****Contact****Name of organization / entity**

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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**

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**