Clinical Trial Protocol
Iranian Registry of Clinical Trials

16 Sep 2026

Comparative bioequivalence study of Fingolimod 0.5 mg capsules manufactured by Zahravi Pharmaceutical Company versus Gilenya® (Novartis Company)

Protocol summary

Study aim

Demonstration of bioequivalence of Fingolimod 0.5 mg Capsule of Zahravi Pharmaceutical Company with Gilenya® capsule manufactured by Novartis company after single dose administration.

Design

Single dose, randomized by lottery Method and crossover bioequivalence study of Fingolimod 0.5 -mg Capsule by Zahravi Co. with Gilenya® (Novartis 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 Fingolimod 0.5-mg capsule in random sequence according to the randomization schedule. The interval between receiving the medicine (washout period) is 60 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، 2، 4، 6، 8 ،10 ، 11، 12، 13، 14، 24 ، 48 and 72 hours after dosing.

Participants/Inclusion and exclusion criteria

Inclusion criteria: Healthy male subjects in the age range of 18-55 years and BMI (Body Mass Index) of 18.5-30. Exclusion criteria: Subjects with BP ≤ 90/60 mm/Hg or BP ≥ 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: Fingolimod 0.5-mg capsule by Zahravi Co. is the test product. Intervention group 2: Gilenya® (Novartis Co.) is the reference product. In each period, 12 of 24 subjects will be given single dose of this product. After the washout period, the volunteers are placed in the opposite group.

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: **IRCT20200407046981N26**
Registration date: **2022-02-22, 1400/12/03**
Registration timing: **prospective**

Last update: **2022-02-22, 1400/12/03**
Update count: **0**

Registration date

2022-02-22, 1400/12/03

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

2022-05-04, 1401/02/14

Expected recruitment end date

2022-07-05, 1401/04/14

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Comparative bioequivalence study of Fingolimod 0.5 mg capsules manufactured by Zahravi Pharmaceutical Company versus Gilenya® (Novartis Company)

Public title

Study of absorption and elimination rate of Fingolimod 0.5-mg capsule in comparison with Fingolimod brand Capsule (Gilenya®).

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 Fingolimod or any ingredients. Subjects with BP ≤ 90/60 mm/Hg or BP ≥ 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

Individuals will be recruited voluntarily through advertising. 24 volunteers are randomly assigned to two sequences by lottery method. A table of random numbers from 1 to 24 is created and the table numbers are assigned to individuals in the order of entry of the candidates on the day of the test. Candidates in two groups with numbers 1-12 and 13-24 will receive reference and test medicine, respectively. After the washout period, the volunteers are placed in the opposite group.

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.1400.813

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، 2، 4، 6، 8 ،10 ، 11، 12، 13، 14، 24 ، 48 and 72 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، 2، 4، 6، 8 ،10 ، 11، 12، 13، 14، 24 ، 48 and 72 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 Fingolimod 0.5-mg capsule produced by Zahravi Co. (Domestic). In each period, 12 of 24 subjects will be given single oral dose of this product. After the washout period, the volunteers are placed in the Intervention group 2. In fact, every single volunteers is used as a control for himself.

Category
Treatment - Drugs

2

Description
Intervention group 2: In this group, volunteers are given a single oral dose of Fingolimod 0.5-mg Capsule (Gilenya), produced by Novartis Company (Brand). In each period, 12 of 24 subjects will be given single oral dose of this product. After the washout period, the volunteers are placed in the Intervention group 1. In fact, every single volunteers is used as control for himself.

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, Daneshghah 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
Pharmaeutics

Street address
Drug Applied Research Center, In front of Shahid Madani Hospital, Daneshghah 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
Isfehan

Province
Isfehan

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 Position

Latest degree
Ph.D.

Other areas of specialty/work
Pharmaceutics

Street address
Drug Applied Research Center, In front of Shahid Madani Hospital, Daneshghah Blvd, Tabriz, Iran

City
Tabriz

Province
East Azarbaijan

Postal code
5165665811

Phone
+98 41 3668 2986

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

Informed Consent Form
No - There is not 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