

Clinical Trial Protocol

Iranian Registry of Clinical Trials

10 Jun 2026

Bioequivalence study of Fingolimod capsule 0.5 mg manufactured by Alborzragos versus originator brand in healthy volunteers in the fasted condition

Protocol summary

Study aim

Bioequivalence Study of fingolimod 0.5mg capsule (glinid) manufactured by Alborzragos company versus originator brand (Tecfidera) manufactured by Biogen

Design

Bioequivalence study, crossover, single-blinded, 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 (72h). The interval between these two periods is 8 weeks. In the first round of the study, the candidates divide into two groups. the first group receives a test capsule and the second group receives a brand capsule. Blood samples are collected immediately before and after drug administration by volunteers. Then, drug extraction is done and samples are ready for analysis. These 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 fingolimod.

Intervention groups

after administration of two capsules manufactured by Alborzragos company, blood sampling is done up to 72h. 8 weeks later, this procedure is performed for 2 brand capsules.

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: **IRCT20200623047902N34**

Registration date: **2023-04-17, 1402/01/28**

Registration timing: **prospective**

Last update: **2023-04-17, 1402/01/28**

Update count: **0**

Registration date

2023-04-17, 1402/01/28

Registrant information

Name

Elham Ghasemian

Name of organization / entity

Country

Iran (Islamic Republic of)

Phone

+98 21 6696 5196

Email address

ghasemian@zistdaru.ir

Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2023-04-21, 1402/02/01

Expected recruitment end date

2023-10-22, 1402/07/30

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Bioequivalence study of Fingolimod capsule 0.5 mg manufactured by Alborzzagros versus originator brand in healthy volunteers in the fasted condition

Public title

Bioequivalence study of Fingolimod capsule 0.5 mg

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:

Smoking History of cardiovascular disease History of liver and kidney disease Alcohol and drug addiction History of allergy to fingolimod

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: **26**

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). Alborzzagros's fingolimod 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

Research Ethics Committees of Tabriz University of Medical Sciences

Street address

International Relations Office, No 2 Central Building, Tabriz University of Medical Sciences, Golgasht Street,

City

Tabriz

Province

East Azarbaijan

Postal code

5165665931

Approval date

2023-02-20, 1401/12/01

Ethics committee reference number

IR.TBZMED.REC.1401.1061

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, 1, 2, 3, 4, 5, 6, 8, 10, 12, 24, 48 and 72 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

This study examines the bioequivalence of fingolimod capsules produced by Alborzagros company versus foreign brand samples. There is only one intervention group and no control group. The intervention group, which includes healthy and fasting volunteers, who will receive a single dose, 2 half-mg capsules made by Alborzagros or Novartis pharmaceutical company, in two 72-hour periods with an interval of 8 weeks. After 8 weeks, the study will continue with another drug.

Category

Treatment - Drugs

2

Description

Control group: single dose, two oral capsules of Geliniya 0.5 mg manufactured by Novartis, as a reference 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, Azadi alley, Moalem st., Abureihan St

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Tabriz

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5154995671

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+98 914 313 5843

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Shokri.j@gmail.com

Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Alborz Zagros company

Full name of responsible person

Amir Hossein Zolfaghari

Street address

No.58, 8th St. Kooye Nasr (Gisha St.)

City

Tehran

Province

Tehran

Postal code

1446863914

Phone

+98 21 4163 7000

Email

A.zolfaghari@alborzzagros.com

Grant name

Grant code / Reference number

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

Yes

Title of funding source

Alborz Zagros 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

Islamic Azad University

Full name of responsible person

Elham Ghasemian

Position

Visiting professor

Latest degree

Ph.D.

Other areas of specialty/work

Medical Pharmacy

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Person responsible for scientific inquiries

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

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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

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