Clinical Trial Protocol
Iranian Registry of Clinical Trials

10 Jun 2026

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

Protocol summary

Study aim

Bioequivalence Study of fingolimod 0.5mg capsule (glinid)manufactured by Alborzzagos 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 Alborzzagros 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

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No.22, first floor, Azadi alley, Moalem st., Abureihan St

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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.)

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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
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Other areas of specialty/work
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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