Clinical Trial Protocol
Iranian Registry of Clinical Trials

07 Nov 2026

Bioequivalence study of Fingolimod 0.5 mg capsule manufactured by Abidi Co (Norabex) versus originator brand Gilenya capsule manufactured by Novartis Co in fasting condition in healthy volunteers

Protocol summary

Study aim

Bioequivalence study of Fingolimod 0.5 mg capsule manufactured by Abidi Co. versus originator brand (Gilenya) manufactured by Novartis in fasting condition in healthy volunteers.

Design

Bioequivalence study, crossover, single-blinded, 24 healthy volunteers. Simple randomization was used for randomization

Settings and conduct

The study is a single-blinded (Volunteers), cross-over and fasting, and on two series of healthy volunteers. The study will be done in two periods (360h). The interval between these two periods is 8 weeks. In the first round of the study, the candidates were divided into two groups the first group received a test capsule and the second group received a brand capsule. In the second round, the first group received a brand capsule and the second group received a test capsule. The blood samples are collected immediately before and after drug administration by volunteers. Then, drug extraction is done and samples are ready for analysis. Sampling is 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

Intervention group 1: Gilenya 0.5 mg capsule manufactured by Novartis as a reference Intervention group 2: Norabex 0.5mg manufactured by Abidi Co. as a test

Main outcome variables

Maximum drug concentration, Time to reach maximum drug concentration

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20200105046010N92**
Registration date: **2024-02-02, 1402/11/13**
Registration timing: **registered_while_recruiting**

Last update: **2024-02-02, 1402/11/13**
Update count: **0**

Registration date

2024-02-02, 1402/11/13

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

2024-01-30, 1402/11/10

Expected recruitment end date

2025-01-29, 1403/11/10

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date
empty

Scientific title
Bioequivalence study of Fingolimod 0.5 mg capsule manufactured by Abidi Co (Norabex) versus originator brand Gilenya capsule manufactured by Novartis Co in fasting condition in healthy volunteers

Public title
Bioequivalence study of Fingolimod 0.5 mg capsule

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 Alcoholism and Narcoticism 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: **2**
Blood sample

Randomization (investigator's opinion)
Randomized

Randomization description
People in the mentioned age group are invited to participate through the advertisement. People are then checked for health and healthy volunteers are identified. People are randomly placed in one of the two study groups with the help of a random number table and receive the intervention related to the same group. The volunteers don't have any information about taking the test drug or brand drug

Blinding (investigator's opinion)
Single blinded

Blinding description
This study is a single-blinded clinical trial (volunteers). Test and Originator brand's 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
Tabriz University of Medical Sciences ethics committe

Street address
Research and technology deputy,3rd floor, No 2 Central Building, Tabriz University of Medical Sciences, Golgasht Street

City
Tabriz

Province
East Azarbaijan

Postal code
5165665931

Approval date
2021-05-17, 1400/02/27

Ethics committee reference number
IR.TBZMED.REC.1400.159

Health conditions studied

1

Description of health condition studied
This study is performed on healthy volunteers and drug concentration in plasma is determined.

ICD-10 code

ICD-10 code description

Primary outcomes

1

Description
Drug plasma concentration

Timepoint
0, 2, 4, 6, 8, 10, 12, 14, 16, 20, 24, 48, 96, 144, 216, 288 and 360h after drug administration

Method of measurement
Liquid Chromatography Mass-Mass

Secondary outcomes

1

Description
Time to reach maximum plasma concentration

Timepoint
After intervention

Method of measurement
Time to reach the maximum drug concentration in plasma 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
Intervention group: single dose, one oral capsule Gilenya 0.5 mg manufactured by Novartis as a reference product. after the washout period, the volunteers receive Norabex 0.5mg capsule manufactured by Abidi Co.
Category
Treatment - Drugs

2

Description
Single dose, Norabex 0.5mg capsule manufactured by Abidi company as a test product. after the washout period, the volunteers receive Gilenya 0.5 mg manufactured by Novartis.
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, Moalem st., Abureihan St
City
Tabriz
Province
East Azarbaijan
Postal code
5154995671
Phone
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Fax
+98 41 3384 2724
Email
shokri.j@gmail.com

Sponsors / Funding sources

1

Sponsor
Name of organization / entity
Abidi Company
Full name of responsible person
Amir Razavian
Street address
8 km of Shahid Lashkari highway, Karaj special road. Obaidi Boulevard No. 72
City
Tehran
Province
Tehran
Postal code
1389776363
Phone
+98 21 4452 2451
Email
info@abidi-diabetes.com
Grant name
Grant code / Reference number
Is the source of funding the same sponsor organization/entity?
Yes
Title of funding source
Abidi 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
Javad Shokri
Position
Professor
Latest degree
Ph.D.
Other areas of specialty/work
Medical Pharmacy
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Person responsible for updating data

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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