

Clinical Trial Protocol

Iranian Registry of Clinical Trials

16 Sep 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 committee

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

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5154995671

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+98 41 3384 2724

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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 scientific inquiries

Contact

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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