

# Clinical Trial Protocol

## Iranian Registry of Clinical Trials

24 Jun 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

##### City

Tabriz

##### Province

East Azarbaijan

##### Postal code

5154995671

##### Phone

+98 914 313 5843

##### 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

##### Street address

No 4, 10th Ave. Boostan Street, Roshdieh

##### City

Tabriz

##### Province

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##### Postal code

5155935357

##### Phone

+98 41 3661 4125

##### Fax

##### Email

shokri.j@gmail.com

## Person responsible for scientific inquiries

### Contact

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Tabriz University of Medical Sciences

**Full name of responsible person**

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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