

Clinical Trial Protocol

Iranian Registry of Clinical Trials

01 Jun 2026

In- Vivo Bioequivalence Study of Dimethyl fumarate 240 mg Enteric-coated test (DIPHOSEL® 240 mg EC. Caps. Abidi, Iran) with brand drug (TECFIDERA® 240 mg, Biogen, Germany) in Iranian healthy volunteers.

Protocol summary

Study aim

In- Vivo Bioequivalence Study of Dimethyl fumarate 240 mg Enteric-coated test (DIPHOSEL® 240 mg EC. Caps. Abidi, Iran) with brand drug (TECFIDERA® 240 mg, Biogen, Germany) in Iranian healthy volunteers.

Design

In-vivo bioequivalence study of test (Dimethyl fumarate 240 mg Enteric-coated Capsules, Abidi, IRAN) in compared with reference drug (TECFIDERA® 240 mg, Biogen, Germany). The single blind, Cross-over, two period, two groups (Intervention and control) and randomized (paper lottery randomization method) study with one week wash-out period.

Settings and conduct

This study will carried out in Simin Baspar Tayf Gostar Company, Tabriz, Iran. The number of participant is 24 healthy Iranian volunteers. This study is single blind by taking the drugs out of their original packaging, the volunteers will not know the The types of receiving drugs (test or brand). This study is a cross over, two periods, two times (each times is 72 hours) with a one-week wash-out period.

Participants/Inclusion and exclusion criteria

Inclusion criteria: participants are between 18-60 years old, Normal body mass index (BMI in the range of 18-28). Exclusion criteria: smoking, History of heart, kidney or liver disease, Pregnancy, Drug addiction

Intervention groups

Single dose Dimethyl fumarate 240 mg Entric-coated Capsules Abidi Pharmaceuticals. Control group: brand drugs (TECFIDERA® 240 mg, Biogen, Germany)

Main outcome variables

Plasma drug concentration

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20200105046010N43**
Registration date: **2021-10-30, 1400/08/08**
Registration timing: **prospective**

Last update: **2021-10-30, 1400/08/08**

Update count: **0**

Registration date

2021-10-30, 1400/08/08

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

2021-11-03, 1400/08/12

Expected recruitment end date

2022-08-03, 1401/05/12

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

In- Vivo Bioequivalence Study of Dimethyl fumarate 240

mg Enteric-coated test (DIPHOSSEL® 240 mg EC. Caps. Abidi, Iran) with brand drug (TECFIDERA® 240 mg, Biogen, Germany) in Iranian healthy volunteers.

Public title

In-vivo Bioequivalence Test of Dimethyl fumarate Capsules with brand drug (TECFIDERA® 240 mg, Biogen, Germany)

Purpose

Treatment

Inclusion/Exclusion criteria

Inclusion criteria:

General health Body mass index between 18-28 Informed consent Being at the age of 18-60 years old

Exclusion criteria:

Smoking History of cardiovascular disease History of liver or kidney disease Pregnancy Alcohol & Drug addiction History of hypersensitivity

Age

From **18 years** old to **60 years** old

Gender

Both

Phase

Bioequivalence

Groups that have been masked

- Participant

Sample size

Target sample size: **24**

Randomization (investigator's opinion)

Randomized

Randomization description

For this reason, A 24- person group will be selected and divided to two 12-person groups randomly. The names of all volunteers will be written on paper pieces and wrapped in aluminum foils. The first 12 papers will randomly be withdrawn from bottle will be selected as group A and others will be categorized in group B.

Blinding (investigator's opinion)

Single blinded

Blinding description

Candidates are not aware of receiving the test drug or brand one. In a one-blind study, information that could distort the test result is hidden from the candidates, but the person in charge of the test is aware of it. Test and brand drug (Dimethyl fumarate Capsules) are withdrawal from their packaging by the executor and placed in similar and coded cans. Volunteers will not be informed about the types of receiving drugs (test or brand).

Placebo

Not used

Assignment

Crossover

Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee

Ethics Committee, Tabriz University of Medical Sciences

Street address

Third floor; Central building; Tabriz University of Medical Sciences; Dneshgah St.

City

Tabriz

Province

East Azarbaijan

Postal code

5166614766

Approval date

2021-05-17, 1400/02/27

Ethics committee reference number

IR.TBZMED.REC.1400.158

Health conditions studied

1

Description of health condition studied

Bioequivalence Study

ICD-10 code

ICD-10 code description

Primary outcomes

1

Description

Plasma drug concentration

Timepoint

Sampling times in this study will be 0, 1, 2, 2:30, 3, 3:20, 3:40, 4, 4:20, 4: 40, 5, 6, 8, 10, 12, 24, 48, 72 hours after prescribing the tablet.

Method of measurement

High Performance Liquid Chromatography tandem mass spectroscopy

Secondary outcomes

empty

Intervention groups

1

Description

Intervention group: they will receive one test drug (Dimethyl fumarate 240 mg Enteric-coated Capsules, ABIDI Pharma. Iran). Blood samples will be taken during 72 hours at the mentioned times after drug administration and the concentration of Dimethyl fumarate in blood samples will be measured by liquid chromatography- Tandem mass spectroscopy method.

Category

Treatment - Other

2

Description

Control group: will receive one test drug (TECFIDERA® 240 mg, Biogen, Germany). Blood samples will be taken from the volunteers during 72 hours at the mentioned times after drug administration and the concentration of Dimethyl fumarate in blood samples will be measured by High performance liquid chromatography- Tandem mass spectroscopy method.

Category

Other

Recruitment centers

1

Recruitment center

Name of recruitment center

Simin Baspar Teyf Gostar Company

Full name of responsible person

Javad Shokri

Street address

No.48, Ferdos square

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Tabriz

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5167874434

Phone

+98 41 3693 4125

Email

Shokri.j@gmail.com

Sponsors / Funding sources

1

Sponsor

Name of organization / entity

ABIDI Pharmaceutical Company

Full name of responsible person

Farzaneh Jalilopur

Street address

8th 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 Pharmaceutical 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

Persons

Person responsible for general inquiries

Contact

Name of organization / entity

Tabriz University of Medical Sciences

Full name of responsible person

Javad Shokri

Position

Full Professor

Latest degree

Ph.D.

Other areas of specialty/work

Medical Pharmacy

Street address

Faculty of Pharmacy, Tabriz University of Medical Sciences, Daneshgah

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Person responsible for scientific inquiries

Contact

Name of organization / entity

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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

Contact

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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 researcher 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

Yes - There is a plan to make this available

Title and more details about the data/document

Only protocol and methods of study are sharable

When the data will become available and for how long

Only protocol and methods of study are shareable.

To whom data/document is available

Pharmaceutical and medical sciences researchers

Under which criteria data/document could be used

Projects information's for any publications is not allowed.

From where data/document is obtainable

By email to the project manager (shokri.j@gmail.com)

What processes are involved for a request to access data/document

This information is confidential and is at the disposal of the project sponsor. Upon request, the information will be provided to the applicant by the contractor's email after the

Comments