

# 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 (DIPHOSEL® 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

##### City

Tabriz

##### Province

East Azarbaijan

##### Postal code

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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##### Phone

+98 41 3334 8489

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Shokri.j@gmail.com

## Person responsible for scientific inquiries

#### Contact

##### Name of organization / entity

Tabriz University of Medical Sciences

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##### Position

Professor

##### Latest degree

Ph.D.

##### Other areas of specialty/work

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## Person responsible for updating data

### Contact

**Name of organization / entity**  
Tabriz University of Medical Sciences  
**Full name of responsible person**  
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**Latest degree**  
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**Other areas of specialty/work**  
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**Province**  
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**Phone**  
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**Email**  
Shokri.j@gmail.com

## 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