

# Clinical Trial Protocol

## Iranian Registry of Clinical Trials

28 May 2026

### Bioequivalence study of Dimethyl fumarate capsule 240 mg manufactured by Alborzragos versus originator brand in healthy volunteers in the fasted condition

#### Protocol summary

##### Study aim

Bioequivalence Study of dimethyl fumarate 240 mg capsule (Tecra) manufactured by Alborzragos company versus originator brand (Tecfidera) manufactured by Biogen

##### Design

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

##### Settings and conduct

The study is a single-blinded, cross-over and fasting, and on two series of healthy volunteers. The study will be done in two periods (10h). The interval between these two periods is one week. In the first round of the study, the candidates divide into two groups. the first group receives a test capsule and the second group receives a brand capsule. Blood samples are collected immediately before and after drug administration by volunteers. Then, drug extraction is done and samples are ready for analysis. These steps are 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 dimethyl fumarate.

##### Intervention groups

Intervention group 1: Tecfidera 240 mg capsule as a reference Intervention group 2: Tecra 240 mg capsule as a test

##### Main outcome variables

Maximum drug concentration; time to reach maximum drug concentration; half-life of drug

#### General information

##### Reason for update

##### Acronym

##### IRCT registration information

IRCT registration number: **IRCT20200623047902N26**

Registration date: **2023-02-10, 1401/11/21**

Registration timing: **prospective**

Last update: **2023-02-10, 1401/11/21**

Update count: **0**

##### Registration date

2023-02-10, 1401/11/21

##### Registrant information

##### Name

Elham Ghasemian

##### Name of organization / entity

##### Country

Iran (Islamic Republic of)

##### Phone

+98 21 6696 5196

##### Email address

ghasemian@zistdaru.ir

##### Recruitment status

**Recruitment complete**

##### Funding source

##### Expected recruitment start date

2023-04-04, 1402/01/15

##### Expected recruitment end date

2023-07-21, 1402/04/30

##### Actual recruitment start date

empty

##### Actual recruitment end date

empty

##### Trial completion date

empty

## Scientific title

Bioequivalence study of Dimethyl fumarate capsule 240 mg manufactured by Alborzagros versus originator brand in healthy volunteers in the fasted condition

## Public title

Bioequivalence study of dimethyl fumarate 240 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 Alcohol and drug addiction History of allergy to dimethyl fumarate

## 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: **26**

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. Each candidate is assigned a number from 1 to 24. The numbers are written on a plastic ball, poured into a container, and mixed. The balls are then removed randomly from the container. The first 12 no.s are considered as (first sequence: Alborzagros's medicine) and the second 12 no.s are considered as (second sequence: originator brand recipient). 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). Alborzagros's dimethyl fumarate and Originator brand 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

Research Ethics Committees of Tabriz University of Medical Sciences

##### Street address

International Relations Office, No 2 Central Building, Tabriz University of Medical Sciences, Golgasht Street,

##### City

Tabriz

##### Province

East Azarbaijan

##### Postal code

5165665931

#### Approval date

2023-02-06, 1401/11/17

#### Ethics committee reference number

IR.TBZMED.REC.1401.983

## Health conditions studied

### 1

#### Description of health condition studied

This study is performed on healthy volunteers.

#### ICD-10 code

#### ICD-10 code description

## Primary outcomes

### 1

#### Description

the concentration of the active metabolite in plasma

#### Timepoint

Pre-dose, 0.33, 0.66, 1, 1.33, 1.66, 2, 2.5, 3, 4, 5, 7, and 10 h 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

The time to reach the maximum metabolite 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 of Tecfidera 240 mg manufactured by Biogen, as a reference product

#### Category

Treatment - Drugs

### 2

#### Description

Intervention group: Single dose, one oral capsule of Tecra 240 mg manufactured by Alborzzagros company as a test product

#### 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, Azadi alley, Moalem st., Abureihan St

##### City

Tabriz

##### Province

East Azarbaijan

##### Postal code

5154995671

##### Phone

+98 914 313 5843

##### Email

Shokri.j@gmail.com

## Sponsors / Funding sources

### 1

#### Sponsor

##### Name of organization / entity

Alborz Zagros company

##### Full name of responsible person

Amir Hossein Zolfaghari

##### Street address

No.58, 8th St. Kooye Nasr (Gisha St.)

##### City

Tehran

##### Province

Tehran

##### Postal code

1446863914

##### Phone

+98 21 4163 7000

##### Email

A.zolfaghari@alborzzagros.com

#### Grant name

#### Grant code / Reference number

#### Is the source of funding the same sponsor organization/entity?

Yes

#### Title of funding source

Alborz Zagros 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

Islamic Azad University

##### Full name of responsible person

Elham Ghasemian

##### Position

Visiting professor

##### Latest degree

Ph.D.

##### Other areas of specialty/work

Medical Pharmacy

##### Street address

Faculty of Pharmacy, Islamic Azad university of Damghan, Cheshme Ali bolivar, Saadi square

##### City

Damghan

##### Province

Semnan

##### Postal code

3671637856

##### Phone

+98 23 3522 5046

##### Fax

##### Email

Ghasemian\_elham@yahoo.com

## Person responsible for scientific inquiries

#### Contact

**Name of organization / entity**

Islamic Azad University

**Full name of responsible person**

Elham Ghasemian

**Position**

Visiting professor

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Ghasemian\_elham@yahoo.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 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