Clinical Trial Protocol
Iranian Registry of Clinical Trials

18 Sep 2026

Bioequivalence study and evaluation of pharmacokinetic parameters of Dimethyl fumarate medicine manufactured by Zistdaru danesh company (Teczifuma 240) versus Tecfidera 240 manufactured by Biogen Company (originator brand) in healthy volunteers

Protocol summary

Study aim

Bioequivalence study of Dimethyl fumarate 240mg manufactured by Zistdaru danesh company (Teczifuma 240mg) versus originator brand (Tecfidera 240mg) manufactured by Biogen company

Design

bioequivalence study, crossover, a blind, 24 healthy volunteers, a simple mu randomized study

Settings and conduct

The study will be conducted in two-way, cross-over and fasting, and on two series of healthy volunteers. The study will be conducted in two 12-hour periods. The interval between these two periods, which is called the wash-out time, is determined by the half-life of the drug plasma, which according to scientific sources at this time should be at least 5 to 7 half-life of the drug. Given that the biological half-life of the drug is in drug form, the time to clear the drug will be two weeks. Blood samples are taken by the doctor immediately before and after the drug is taken by the volunteers, and the steps for preparing the samples include plasma separation and drug extraction to analyze the amount of drug on them.

Participants/Inclusion and exclusion criteria

Healthy volunteers 18-60 years old

Intervention groups

In this study, two groups of intervention and control are not applicable. Both groups will receive test-reference medicine and testing on two different occasions, and therefore the test results will be independent of individual differences and will only indicate differences in the formulation of the two drugs.

Main outcome variables

maximum drug concentration, time to reach to maximum drug concentration, half life of drug

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20200623047902N1**
Registration date: **2020-06-26, 1399/04/06**
Registration timing: **prospective**

Last update: **2020-06-26, 1399/04/06**
Update count: **0**

Registration date

2020-06-26, 1399/04/06

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

2020-06-30, 1399/04/10

Expected recruitment end date

2020-09-20, 1399/06/30

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title
Bioequivalence study and evaluation of pharmacokinetic parameters of Dimethyl fumarate medicine manufactured by Zistdaru danesh company (Teczifuma 240) versus Tecfidera 240 manufactured by Biogen Company (originator brand) in healthy volunteers

Public title
Bioequivalence study of Dimethyl fumarate capsule manufactured by Zistdaru danesh company (Teczifuma 240mg) in Iranian healthy volunteers
Purpose
Treatment
Inclusion/Exclusion criteria
Inclusion criteria:
General Health (Liver, Heart and Kidney), Body Mass Index (18-28), Conscious Consciousness, Age (18-60)
Exclusion criteria:
Smoking, history of cardiovascular disease, history of liver and kidney disease, pregnancy, alcohol and drug addiction, history of drug allergy
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**
More than 1 sample in each individual
Number of samples in each individual: **30**
Blood sample
Randomization (investigator's opinion)
Randomized
Randomization description
People in different age groups are invited to collaborate through the advertisement. Then people are selected and individuals in each group randomly selected from the qualified people to participate in the project. The first twelve are considered as (first sequence: Teczifuma recipient) and the second twelve are considered as (second sequence:Tecfidera recipient).
Blinding (investigator's opinion)
Single blinded
Blinding description
This study is a blind side clinical trial (volunteers). Tecfidera and Teczifuma 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
Ethics committee of Islamic Azad University-Damghan Branch
Street address
Zistdaru danesh Co., Second floor, No.98, Bozorgmehr St., Velsale Shirazi st., Enghelan St.
City
Tehran
Province
Tehran
Postal code
1417833714
Approval date
2019-04-24, 1398/02/04
Ethics committee reference number
IR.IAU.DAMGHAN.REC.1398.004

Health conditions studied

1

Description of health condition studied
In this study, the disease is not examined. The subject of the study is the bioequivalence study of the Dimethyl Fumarate capsule of test and reference in healthy volunteers.
ICD-10 code
ICD-10 code description

Primary outcomes

1

Description
Determination of concentration of active form of drug in bood
Timepoint
After taking blood sample
Method of measurement
HPLC-MASS MASS

Secondary outcomes

empty

Intervention groups

1

Description
Intervention Group 1: Volunteers take Teczifuma capsule drug, which is manufactured by Zistdaru danesh Company and contains 240 mg of dimethyl fumarate,as a

test product, as a single oral dose, and at the specified time, they are taken blood and the concentration of the active form of the drug in the blood is determined.

Category

Treatment - Drugs

2

Description

Intervention Group 2: Volunteers take Tecfidera capsule drug, which is manufactured by Biogen Company and contains 240 mg of dimethyl fumarate, as a reference product, as a single oral dose, and at the specified time, they are taken blood and the concentration of the active form of the drug in the blood is determined.

Category

Treatment - Drugs

Recruitment centers

1

Recruitment center

Name of recruitment center

Zistdaru danesh Co.

Full name of responsible person

Sima Sadrai

Street address

School of Pharmacy, Tehran University of Medical Sciences

City

Tehran

Province

Tehran

Postal code

14155/6451

Phone

+98 21 6695 9054

Email

sadrai@tums.ac.ir

Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Zistdaru danesh Co.

Full name of responsible person

Hooshmand Ilka

Street address

No. 10, 8th floor, Faraz building, Sahand St., Beheshti St.

City

Tehran

Province

Tehran

Postal code

1559836438

Phone

+98 21 4231 8100

Email

ilka@Zistdaru.ir

Grant name

Grant code / Reference number

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

Yes

Title of funding source

Zistdaru danesh Co.

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

Zistdaru danesh Co.

Full name of responsible person

Elham Ghasemian

Position

Deputy director of research and development

Latest degree

Ph.D.

Other areas of specialty/work

Medical Pharmacy

Street address

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Province

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Postal code

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Email

ghasemian@zistdaru.ir

Person responsible for scientific inquiries

Contact

Name of organization / entity

Zistdaru danesh Co

Full name of responsible person

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Person responsible for updating data

Contact

Name of organization / entity
Zistdaru danesh Co

Full name of responsible person
Elham Ghasemian

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Email
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Sharing plan

Deidentified Individual Participant Data Set (IPD)
Yes - There is a plan to make this available

Study Protocol
Yes - There is a plan to make this available

Statistical Analysis Plan
Undecided - It is not yet known if there will be a plan to make this available

Informed Consent Form
Yes - There is a plan to make this available

Clinical Study Report
Yes - There is a plan to make this available

Analytic Code
Undecided - It is not yet known if there will be a plan to make this available

Data Dictionary
Undecided - It is not yet known if there will be a plan to make this available

Title and more details about the data/document
blood concentration data

When the data will become available and for how long
8 months after publication of results

To whom data/document is available
University researchers

Under which criteria data/document could be used
Do similar studies

From where data/document is obtainable
Elham Ghasemian Ghasemian@zistdaru.ir

What processes are involved for a request to access data/document
After evaluation of reasons to apply, it will be sent during 60 working days

Comments