Clinical Trial Protocol
Iranian Registry of Clinical Trials

07 Nov 2026

Bioequivalence study of Miglustat 100 mg capsule (Miglutan)manufactured by Zistdaru Danesh versus originator brand (Zavesca) in healthy volunteers in the fasted condition

Protocol summary

Study aim

Bioequivalence Study of Miglustat 100 mg capsule manufactured by Zistdaru Danesh company (Miglutan) versus originator brand (Zavesca) manufactured by Janssen company

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 (48h). 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. In the second period, the first group will consume the brand capsule, and the second group will consume the test capsule. 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 Miglustat

Intervention groups

Intervention group 1: Zavesca 100mg capsule manufactured by Janssen company as a reference Intervention group 2: Miglutan 100 mg capsule manufactured by Zistdaru Danesh company as a test. Volunteers are divided into 2 groups. The first group consumes test medicine and the second group consumes brand one. In the second period which is run after one week, the first group will consume the brand and the second group will consume the test medicine.

Main outcome variables

Maximum drug concentration, Time to reach maximum concentration, Half-life of drug

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20200105046010N76**
Registration date: **2023-05-27, 1402/03/06**
Registration timing: **prospective**

Last update: **2023-05-27, 1402/03/06**
Update count: **0**

Registration date

2023-05-27, 1402/03/06

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

2023-06-22, 1402/04/01

Expected recruitment end date

2024-03-19, 1402/12/29

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Bioequivalence study of Miglustat 100 mg capsule (Miglutan)manufactured by Zistdaru Danesh versus originator brand (Zavesca) in healthy volunteers in the fasted condition

Public title

Bioequivalence study of Miglustat 100 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 Miglustat

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: **34**

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: Zistdaru Danesh'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. In the second period that is run after one week, the First group will consume brand medicine and the second group will consume test one.

Blinding (investigator's opinion)

Single blinded

Blinding description

This study is a single-blinded clinical trial (volunteers). Zistdaru Danesh's Miglustat 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

Tabriz University of Medical Sciences Ethics Committee

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

2023-05-22, 1402/03/01

Ethics committee reference number

IR.TBZMED.REC.1402.167

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

Plasma concentration of the drug

Timepoint

Before and 0.5, 1, 1.5, 2, 2.5, 3, 3.5, 4, 4.5, 5, 6, 8, 10, 12, 24 and 48h 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 of Zavesca 100mg manufactured by Janssen company, as a reference product
Category
Treatment - Drugs

2

Description
Intervention group: Single dose, one oral Miglutan 100 mg capsule manufactured by Zistdaru Danesh company as a test product. Volunteers are divided into 2 groups. The first group consumes test medicine and the second group consumes brand one. In the second period which is run after one week, the first group will consume brand and second group consume test medicine.
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
Email
shokri.j@gmail.com

Sponsors / Funding sources

1

Sponsor
Name of organization / entity
Zistdaru danesh Co.
Full name of responsible person
Hooshmand Ilka
Street address
No. 404, 4th floor, Rose mall complex, Kharazi highway
City
Tehran
Province
Tehran
Postal code
1498711347
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
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
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Person responsible for updating data

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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