

Clinical Trial Protocol

Iranian Registry of Clinical Trials

17 Sep 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

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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

Street address

No 4, 10th Ave. Boostan Street, Roshdih, Tabriz

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Person responsible for scientific 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
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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 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