Clinical Trial Protocol
Iranian Registry of Clinical Trials

09 Jun 2026

Study of bioequivalence of 100mg Miglustat capsule in healthy volunteers after single dose oral administration

Protocol summary

Study aim
Determination of plasma concentration of 100 mg Miglustat capsule generic product of Pharan shimi Company and 100 mg Zavesca capsule reference Product of ALMAC PHARMA-UK

Design
This study is a bioequivalence phase of clinical trial with control and cross over groups which is double-blinded and randomized and will be performed on 24 healthy subjects including 12 in control group and 12 in intervention group. For randomization, simple and restricted random allocation law is used.

Settings and conduct
This study is carried out at Shahid Beheshti School of Pharmacy, which has been the site of many similar studies. After receiving the drug orally , blood samples are taken from the volunteers at different times and the plasma concentration of the drug is measured by LC mass. In this double-blind study, volunteers, personnel and responsible physician is unaware for the type of drug and only the person responsible is aware of the type of drug. To ensure blinding, the drugs are removed from the box and both types are similar in appearance.

Participants/Inclusion and exclusion criteria
Inclusion criteria: Healthy volunteers aged 18 to 50 years old. Exclusion criteria: History of liver, kidney and cardiovascular diseases that can affect drug clearance from body; History of taking any medication in the last two weeks; Creatinine above 2

Intervention groups
Intervention group: oral intake of 100 mg Miglustat capsule generic product of Pharan shimi Company with one dose and evaluation of plasma concentration up to 24 hours in the blood of healthy volunteers. Control group: oral intake of 100 mg Zavesca capsule reference Product of ALMAC PHARMA-UK with one dose and evaluation of plasma concentration up to 24 hours in the blood of healthy volunteers.

Main outcome variables
Maximum plasma concentration of the drug

General information

Reason for update

Acronym

IRCT registration information
IRCT registration number: **IRCT20210201050197N7**
Registration date: **2023-12-24, 1402/10/03**
Registration timing: **prospective**

Last update: **2023-12-24, 1402/10/03**
Update count: **0**

Registration date
2023-12-24, 1402/10/03

Registrant information

Name
Azadeh Haeri

Name of organization / entity

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Iran (Islamic Republic of)

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Recruitment status
Recruitment complete

Funding source

Expected recruitment start date
2024-01-05, 1402/10/15

Expected recruitment end date
2024-06-04, 1403/03/15

Actual recruitment start date
empty

Actual recruitment end date
empty

Trial completion date

empty

Scientific title
Study of bioequivalence of 100mg Miglustat capsule in healthy volunteers after single dose oral administration

Public title
Bioequivalence of Miglustat capsule
Purpose
Basic scienece
Inclusion/Exclusion criteria
Inclusion criteria:
Healthy volunteer Age_18-50 year
Exclusion criteria:
History of liver, kidney and cardiovascular diseases that can affect drug clearance from body History of taking any medication in the last two weeks Creatinine above 2
Age
From **18 years** old to **50 years** old
Gender
Both

Phase
Bioequivalence
Groups that have been masked

- Participant
- Care provider
- Outcome assessor
- Data analyser

Sample size
Target sample size: **24**
More than 1 sample in each individual
Number of samples in each individual: **2**
Each healthy volunteer receives 100 mg Miglustat capsules made by Pharan shimi Company once and after one week, Zavesca capsules 100 mg made by the ALMAC PHARMA-UK company or vice versa.
Randomization (investigator's opinion)
Randomized
Randomization description
In order to randomize in this study, simple and restricted random allocation rule will be used. This method represents a large block for the total sample size, meaning that the balance in the number of people assigned to each group will be achieved at the end. For this purpose, first, 24 candidates who meet the inclusion criteria will be selected. Then, 12 lotteries for the intervention group and 12 lotteries for the control group will be placed inside a lottery container. Then, randomly, each of these 24 individuals will take a lottery out of the container without replacement and deliver the lottery to the project officer and the allocation of the group to the individual will be determined (the person, physician and nurse responsible are not aware of the allocation of the group to the individual). In the second phase of the study, the person in the control group will be transferred to the intervention group and vice versa.
Blinding (investigator's opinion)
Double blinded
Blinding description
Volunteers and study physician are not aware of what products they have received at any time. Since the drug is removed from its box and blister and give to the volunteers, they will not know the type of medicine. The new drug are similar to the reference drug in terms of color, smell, flavor and consistency and all the apparent properties so that participants do not know the type of drug.
Placebo
Not used
Assignment
Crossover
Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee
Name of ethics committee
School of Pharmacy Nursing and Midwifery, Shahid Beheshti Medical University
Street address
No:2660, Faculty of Pharmacy, Shahid beheshti university of medical scineces, Nyayesh complex, Valiasr st.
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Tehran
Province
Tehran
Postal code
1996835113
Approval date
2023-11-13, 1402/08/22
Ethics committee reference number
IR.SBMU.PHARMACY.REC.1402.165

Health conditions studied

1

Description of health condition studied
ICD-10 code
ICD-10 code description

Primary outcomes

1

Description
Maximum plasma concentration of the drug
Timepoint
Before intervention and 0.5, 1, 1.5, 2, 2.5, 3, 4, 6, 8, 10, 12 and 24 hours after intervention
Method of measurement
liquid chromatography-mass (LC-MS) device

Secondary outcomes

empty

Intervention groups

1

Description
Intervention group: In this group, 12 volunteers receive a 100 mg Miglustat capsule made by Pharan shimi Company. Up to 24 hours, blood samples will be taken from the volunteers and plasma concentration of the drug will be measured by liquid chromatography. Each time, 5 cc blood samples are taken from volunteers. Then these 12 volunteers will enter the control group after one week.

Category
Other

2

Description
Control group: In this group, 12 volunteers receive 100mg Zavesca capsule made by ALMAC PHARMA-UK company. Up to 24 hours, blood samples will be taken from the volunteers and plasma concentration of the drug will be measured by liquid chromatography. Each time, 5 cc blood samples are taken from volunteers. Then these 12 volunteers will enter the intervention group after one week.

Category
Other

Recruitment centers

1

Recruitment center

Name of recruitment center
School of Pharmacy, Shahid Beheshti University of Medical Sciences

Full name of responsible person
Azadeh Haeri

Street address
No 2660, School of Pharmacy Nursing and Midwifery, Shahid Beheshti Medical University, Niayesh building, Valiasr Ave

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Sponsors / Funding sources

1

Sponsor

Name of organization / entity
Shahid Beheshti University of Medical Sciences

Full name of responsible person
Afshin Zarghi

Street address
5th Floor, Bldg No.2 SBMU, Arabi abbas Ave, Yaman Blvd, Chamran Blvd

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Grant name

Grant code / Reference number

Is the source of funding the same sponsor organization/entity?
No

Title of funding source
Shahid Beheshti University of Medical Sciences

Proportion provided by this source
100

Public or private sector
Public

Domestic or foreign origin
Domestic

Category of foreign source of funding
empty

Country of origin

Type of organization providing the funding
Academic

Person responsible for general inquiries

Contact

Name of organization / entity
Shahid Beheshti University of Medical Sciences

Full name of responsible person
Azadeh Haeri

Position
Associate professor

Latest degree
Ph.D.

Other areas of specialty/work
Medical Pharmacy

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Person responsible for scientific inquiries

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Name of organization / entity
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Full name of responsible person
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Position
Associate professor

Latest degree
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Other areas of specialty/work
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Person responsible for updating data

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Sharing plan

Deidentified Individual Participant Data Set (IPD)
Undecided - It is not yet known if there will be a plan to make this available

Study Protocol
Undecided - It is not yet known if there will be 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
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