Clinical Trial Protocol
Iranian Registry of Clinical Trials

16 Sep 2026

A study to compare the relative bioavailability of Fatak Chemie Pars and Bayer formulations of acarbose 100 mg tablets in 24 healthy adult volunteers under fasting conditions

Protocol summary

Study aim

The study aims to evaluate the bioequivalence of acarbose 100 mg tablets produced by two different pharmaceutical companies under fasting conditions

Design

This 3-way, crossover study is conducted to compare the pharmacodynamics of acarbose and Glucobay® tablets in 24 healthy adult volunteers. Volunteers will be sorted and receive a number from 1 to 24. In each phase of the study, 8 volunteers will receive sucrose and 8 person will receive acarbose manufactured by Fatak Chemie Pars company plus sucrose and the remaining 8 volunteers will receive Glucobay® manufactured by Bayer company plus sucrose. The administered drugs will be replaced in each phase of the study.

Settings and conduct

The dose administration and subsequent sample collection will be performed in Motahhari hospital (Gonbade Kavous, Iran).

Participants/Inclusion and exclusion criteria

Inclusion criteria: aged 18-55 years; subject available for the entire study period; willingness to adhere to protocol requirements as evidenced by written informed consent; good health at screening. Exclusion criteria: History of use of any drug; hypersensitivity or intolerance; significant history or current evidence of chronic disease.

Intervention groups

First intervention group: A single dose of 75 g of sucrose to 8 subjects. Second intervention group: A single 100 mg dose of acarbose manufactured by Fatak Chemie Pars company plus 75 g of sucrose to 8 subjects. Third intervention group: A single 100 mg dose of Glucobay manufactured by Bayer company plus 75 g of sucrose to 8 subjects. Since in this study, the volunteers will receive both test and reference drugs, each volunteer will act as his own control. There will be a time interval of 1 week between interventions.

Main outcome variables

Glucose plasma concentration; Area under the plasma concentration-time curve

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20130626013776N72**
Registration date: **2022-07-20, 1401/04/29**
Registration timing: **prospective**

Last update: **2022-07-20, 1401/04/29**
Update count: **0**

Registration date

2022-07-20, 1401/04/29

Registrant information

Name

Hossein Amini

Name of organization / entity

Golestan University of Medical Sciences

Country

Iran (Islamic Republic of)

Phone

+98 17 1442 1651

Email address

hamini@sbmu.ac.ir

Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2022-10-23, 1401/08/01

Expected recruitment end date

2023-08-23, 1402/06/01

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

A study to compare the relative bioavailability of Fatak Chemie Pars and Bayer formulations of acarbose 100 mg tablets in 24 healthy adult volunteers under fasting conditions

Public title

Bioequivalence study of acarbose 100 mg tablets

Purpose

Basic scienece

Inclusion/Exclusion criteria

Inclusion criteria:

18-55 years of age. The subject is able and willing to provide signed informed consent. The subject is available for the entire study period. Willing to adhere to protocol requirements as evidenced by written informed consent. The subject has a stable residence and telephone. Good health as determined by lack of clinically significant abnormalities in health assessments performed at screening.

Exclusion criteria:

History of allergy or sensitivity to acarbose. History of any drug hypersensitivity or intolerance which, in the opinion of the investigator,would compromise the safety of the subject of the study. Significant history or current evidence of chronic infectious disease, system disorder or organ dysfunction. Presence of gastrointestinal disease or history of malabsorption within the last year. History of a medical disorders occurring within the last year that required hospitalization or medication. Use of pharmacologic agents known to significantly induce or inhibit drug-metabolizing enzymes within 30 days prior to dosing. Receipt of any drug as part of a research study within 30 days prior to the present study. Donation or significant loss of whole blood (480 ml or more) within 30 days prior to the present study.

Age

From **18 years** old to **55 years** old

Gender

Both

Phase

Bioequivalence

Groups that have been masked

No information

Sample size

Target sample size: **24**

More than 1 sample in each individual

Number of samples in each individual: **2**

In a crossover design, each person is its own control and receives two different interventions

Randomization (investigator's opinion)

Randomized

Randomization description

A pot randomization method will be used in this study. 12 papers are labeled "Reference Product" and 12 papers are written as "Test Product". The papers are then placed in sealed envelopes, and participants randomly select a paper and will be placed in the Reference or Test groups.

Blinding (investigator's opinion)

Not blinded

Blinding description

Placebo

Not used

Assignment

Crossover

Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee

Ethics Committee of Golestan University of Medical Sciences

Street address

Falsafi Building, Sari Road Km 2

City

Gorgan

Province

Golestan

Postal code

4934174515

Approval date

2022-06-12, 1401/03/22

Ethics committee reference number

IR.GOUMS.REC.1401.113

Health conditions studied

1

Description of health condition studied

.

ICD-10 code

ICD-10 code description

Primary outcomes

1

Description

Plasma glucose concentration

Timepoint

At time -15, 0, 10, 20, 30, 40, 50, 60 minutes, and then 1.25, 1.5, 2, 2.5, 3, 3.5 and 4 hours after drug administratio

Method of measurement

Blood sampling and measurement of plasma glucose concentrations

2

Description
Area under plasma glucose concentration-time curve
Timepoint
At time -15, 0, 10, 20, 30, 40, 50, 60 minutes, and then 1.25, 1.5, 2, 2.5, 3, 3.5 and 4 hours after drug administratio
Method of measurement
Blood sampling and measurement of plasma glucose concentrations

Secondary outcomes

1

Description
Time to reach maximum plasma glucose concentration
Timepoint
By selecting highest plasma glucose concentrations at time -15, 0, 10, 20, 30, 40, 50, 60 minutes after drug administration
Method of measurement
Blood sampling and measurement of plasma glucose

Intervention groups

1

Description
Intervention group 1: Oral administration of a single dose of 75 g of sugar to healthy volunteers under fasting conditions in the morning of the experiment day
Category
Placebo

2

Description
Intervention group 2: Oral administration of a single dose of 75 g of sugar and 100 mg dose of acarbose (1 tablet) manufactured by Fatak Chemie Pars to healthy volunteers under fasting conditions in the morning of the experiment day
Category
Treatment - Drugs

3

Description
Intervention group 3: Oral administration of a single dose of 75 g of sugar and 100 mg dose of Glucobay (1 tablet) manufactured by Bayer to healthy volunteers under fasting conditions in the morning of the experiment day
Category
Treatment - Drugs

Recruitment centers

1

Recruitment center
Name of recruitment center
Dialysis Center, S. Motahhari Hospital
Full name of responsible person
Yahya Naserifard
Street address
Taleghani Street
City
Gonbade Kavous
Province
Golestan
Postal code
4916817693
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Fax
+98 17 3252 5972
Email
haminhplc@yahoo.com

Sponsors / Funding sources

1

Sponsor
Name of organization / entity
Fatak Chemie Pars Pharmaceuticals
Full name of responsible person
Dr. Maryam Karimi
Street address
Valiasr Street, Tavakkol Street, Semnan Industrial estate
City
Semnan
Province
Semnan
Postal code
14578-6687
Phone
+98 23 3365 1021
Fax
+98 23 3365 1021
Email
info@fatakchemie.com
Web page address
https://fatakchemie.com/
Grant name
Bioequivalence Study of Acarbose
Grant code / Reference number
Is the source of funding the same sponsor organization/entity?
No
Title of funding source
Fatak Chemie Pars Pharmaceuticals
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
Gorgan University of Medical Sciences
Full name of responsible person
Hossein Amini
Position
Associate 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
Data are confidential and need permission from the company.
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