Clinical Trial Protocol
Iranian Registry of Clinical Trials

17 Sep 2026

In- Vivo Bioequivalence study of Empagliflozin, Linagliptin tablet 25,5mg ABIDI (Glorenta 25, 5mg) with brand drugs (Glyxambi 25, 5mg Boehringer Ingelheim, Gremany) in Iranian healthy volunteers.

Protocol summary

Study aim

In Vivo Bioequivalence study of Empagliflozin, Linagliptin tablet 25, 5mg ABIDI (Glorenta 25, 5mg) with brand drugs (Glyxambi 25, 5mg Boehringer Ingelheim, Gremany) in Iranian healthy volunteers.

Design

Single dose, randomized, two sequences, two period crossover with a washout period.

Settings and conduct

This study will be conducted in two-way, cross-over and fasting, and on two sets of healthy volunteers. The study will be conducted in two periods of twenty-four hours.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 should be at least 5 to 7 half-life of the drug in the case of the drug under study. The plan will take a week to clean up the drug, given the biological half-life of the drugs in the drug form.In the first round, candidates are divided into two groups, and the first group receives a test tablet and the second group receives a similar tablet. Blood samples will taken by the volunteer by the technician immediately after taking the drug, and the preparation steps of the samples, including plasma separation and drug extraction, are performed to analyze the amount of drug on them.

Participants/Inclusion and exclusion criteria

24 participants will be selected from non-smoking, not pregnant people with no history of heart, kidney and liver disease or dis functions with both sex (male&female). The ages and BMIs of participant should be in the range of 18-60 and 18-25 respectively.

Intervention groups

Both groups received in cross-over design medication and testing at two different cross-sections and Therefor,the test results are independent of individual differences and it will only show the difference in the formulation of the two drugs.

Main outcome variables

Cmax,Tmax, T1/2, Ke (Elemination)

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20200105046010N4**
Registration date: **2020-06-21, 1399/04/01**
Registration timing: **prospective**

Last update: **2020-06-21, 1399/04/01**
Update count: **0**

Registration date

2020-06-21, 1399/04/01

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

2020-09-04, 1399/06/14

Expected recruitment end date

2021-05-04, 1400/02/14

Actual recruitment start date

empty

Actual recruitment end date
empty
Trial completion date
empty

Scientific title
In- Vivo Bioequivalence study of Empagliflozin, Linagliptin tablet 25,5mg ABIDI (Glorenta 25, 5mg) with brand drugs (Glyxambi 25, 5mg Boehringer Ingelheim, Gremany) in Iranian healthy volunteers.

Public title
Empagliflozin, Linagliptin tablet 25, 5mg ABIDI (Glorenta 25, 5mg), In- Vivo Bioequivalence in Iranian healthy volunteers.
Purpose
Treatment
Inclusion/Exclusion criteria
Inclusion criteria:
General health(liver, heart, kidney) Body mass index(18-28) Informed consent Age(18-60)
Exclusion criteria:
Smoking A history of cardiovascular disease A history of liver & kidney disease Pregnancy Alcohol & Drug addiction Hypersensitivity to the drug
Age
From **18 years** old to **60 years** old
Gender
Both

Phase
Bioequivalence
Groups that have been masked
No information
Sample size
Target sample size: **24**
Randomization (investigator's opinion)
Randomized
Randomization description
People in different age groups are invited to cooperate through the advertisement.Then people are selected. Individuals will be randomly selected through advertisements. The number of individuals will be randomly selected and the first twelve will be selected as the first sequence and the second twelve will be selected as the second sequence.
Blinding (investigator's opinion)
Single blinded
Blinding description
Candidates are not aware of the test drug or brand name.
Placebo
Not used
Assignment
Crossover
Other design features
Tow period / Tow sequence with a washout time

Secondary Ids

empty

Ethics committees

1

Ethics committee
Name of ethics committee
Tabriz University of Medical Sciences Ethics Committee
Street address
Tabriz. No. 48, Ferdows Square, Ferdows St.
City
Tabriz
Province
East Azarbaijan
Postal code
51678744
Approval date
2019-11-24, 1398/09/03
Ethics committee reference number
IR.TBZMED.REC.1398.911

Health conditions studied

1

Description of health condition studied
In this study the bioequivalence of test and brand of Glorenta® will evaluated.
ICD-10 code
ICD-10 code description

2

Description of health condition studied
In this study the bioequivalence of test and brand of Glorenta® will evaluated.
ICD-10 code
ICD-10 code description

Primary outcomes

1

Description
Drug analysis in plasma or whole blood
Timepoint
After blood sampling
Method of measurement
HPLC,LC-MS/MS or UPLC-MS/MS

Secondary outcomes

empty

Intervention groups

1

Description
Intervention group: Single-dose ampagliflozin, Linagliptin 25.5 mg tablets (Glyxambi® 25, 5mg. Boehringer Ingelheim, Germany) as reference product.

Category
Treatment - Drugs

Recruitment centers

1

Recruitment center
Name of recruitment center
Simin Baspar Teyf Gostar Company
Full name of responsible person
Javad Shokri
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No.48,Ferdos Street
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Shokri.j@gmail.com

Sponsors / Funding sources

1

Sponsor
Name of organization / entity
Tabriz University of Medical Sciences
Full name of responsible person
Amir Razavian
Street address
8 km of Shahid Lashkari highway, Karaj special road. Obaidi Boulevard No. 72
City
Tehran
Province
Tehran
Postal code
1389776363
Phone
+98 21 4452 2451
Email
info@abidi-diabetes.com
Grant name
Grant code / Reference number
Is the source of funding the same sponsor organization/entity?
Yes
Title of funding source
Tabriz University of Medical Sciences
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
Other

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
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Other areas of specialty/work
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Person responsible for updating data

Contact
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Full name of responsible person

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Position

Professor

Latest degree

Ph.D.

Other areas of specialty/work

Medical Pharmacy

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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 date are as secure between researcher 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

Yes - There is a plan to make this available

Title and more details about the data/document

Only protocol and methods of study are sharable.

When the data will become available and for how long

After finishing of the protocol (Probably 6 months receiving IRCT code)

To whom data/document is available

Pharmaceutical and medical sciences researchers.

Under which criteria data/document could be used

Projects information's for any publications is not allowed.

From where data/document is obtainable

Contact with E-mail of the main researcher.

What processes are involved for a request to access data/document

Personal and academic details and the aim of the request.

Comments