Clinical Trial Protocol
Iranian Registry of Clinical Trials

14 Jul 2026

In-vivo Bioequivalence Study of Linagliptin/Metformin 2.5/1000 mg FC. Tablets of The Test Drug (Kharazmi Pharma, Iran) in Compared with The Reference Drug (Jentadueto® 2.5/1000 mg, Boehringer Ingelheim, Germany) in fasting condition in healthy volunteers

Protocol summary

Study aim

In-vivo Bioequivalence Study of Linagliptin/Metformin 2.5/1000 mg FC. Tablets of The Test Drug (Kharazmi Pharma, Iran) in Compared with The Reference Drug (TRAJENTA DUO® 2.5/1000 mg, Boehringer Ingelheim, Germany) in fasting condition in healthy volunteers.

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 (72h). The interval between these two periods is two week. The candidates were divided into two groups in the first round of the study. the first group receives a test tablet and the second group receives a brand tablet. Blood samples are collected immediately before and after drug administration by volunteers. Then, drug extraction is done and samples are ready for analysis. 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 kg/m^2); 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 Linagliptin or Metoformin

Intervention groups

Intervention group 1: TRAJENTA DUO® 2.5/1000 mg tablet as a reference Intervention group 2: Linagliptin/Metformin 2.5/1000 mg as a test

Main outcome variables

Maximum drug concentration, Time to reach maximum drug concentration

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20200105046010N101**
Registration date: **2024-03-03, 1402/12/13**
Registration timing: **prospective**

Last update: **2024-03-03, 1402/12/13**
Update count: **0**

Registration date

2024-03-03, 1402/12/13

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

2024-04-20, 1403/02/01

Expected recruitment end date

2025-04-21, 1404/02/01

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title
In-vivo Bioequivalence Study of Linagliptin/Metformin 2.5/1000 mg FC. Tablets of The Test Drug (Kharazmi Pharma, Iran) in Compared with The Reference Drug (Jentadueto® 2.5/1000 mg, Boehringer Ingelheim, Germany) in fasting condition in healthy volunteers

Public title
Bioequivalence Study of Linagliptin/Metformin 2.5/1000 mg FC. Tablets of The Test Drug (Kharazmi Pharma, Iran)

Purpose
Treatment

Inclusion/Exclusion criteria

Inclusion criteria:
General Health (Liver, Heart, and Kidney) Body Mass Index (18-28) kg/m^2 Informed consent Age (18-55 years old)

Exclusion criteria:
Nicotine consumption history Cardiovascular disease History Liver and kidney disease History Alcohol and opioid addiction Allergy reactions history to Linagliptin or Metformin

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: **28**
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 and 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: Kharazmi's medicine) and the second 12 no.s are considered as (first sequence: originator brand recipient). The volunteers don't have any information about taking the test drug or brand drug

Blinding (investigator's opinion)
Single blinded

Blinding description
This study is a single-blinded clinical trial (volunteers). Test and Originator brand's tablets 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 committe

Street address
Research and technology deputy,3rd floor, No 2 Central Building, Tabriz University of Medical Sciences, Golgasht Street

City
Tabriz

Province
East Azarbaijan

Postal code
5165665931

Approval date
2024-01-14, 1402/10/24

Ethics committee reference number
IR.TBZMED.REC.1402.794

Health conditions studied

1

Description of health condition studied
This study is performed on healthy volunteers and drug concentration in plasma is determined.

ICD-10 code

ICD-10 code description

Primary outcomes

1

Description
Drug plasma concentration

Timepoint
0، 1، 1.5، 2، 2.5، 0،3، 3.5، 4.0، 6.0، 8، 10، 12، 24، 48 72 h 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 The Reference Drug (TRAJENTA DUO® 2.5/1000 mg, Boehringer Ingelheim, Germany). after washout period, the volunteers receive Linagliptin/Metoformin 1000/2.5 tablet manufactured by Kharazmi Co.
Category
Treatment - Drugs

2

Description
Intervention group: Single dose, one oral Linagliptin/Metoformin 1000/2.5 mg tablet manufactured by Kharazmi company as test product.after washout period, the volunteers receive TRAJENTA DUO® 2.5/1000 mgBoehringer Ingelheim, Germany
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
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5154995671
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+98 914 313 5843
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shokri.j@gmail.com

Sponsors / Funding sources

1

Sponsor
Name of organization / entity
Kharazmi Pharmacy
Full name of responsible person
Peymn Tarrahomi
Street address
No. 115 Kharazmi Pharmacy Deadlock, Shahid Gholamreza Jalal St., Esteghlal Town
City
Tehran
Province
East Azarbaijan
Postal code
1389716512
Phone
+98 21 4454 5413
Email
info@kharazmipharm.com
Grant name
Grant code / Reference number
Is the source of funding the same sponsor organization/entity?
Yes
Title of funding source
Kharazmi Pharmacy
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
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 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