

Clinical Trial Protocol

Iranian Registry of Clinical Trials

08 Jun 2026

Bioequivalence study of Linagliptin 5mg tablet manufactured by Kharazmi Co versus originator brand (Trajenta) manufactured by Boehringer in fasting condition in healthy volunteers

Protocol summary

Study aim

Bioequivalence study of Linagliptin 5mg tablet manufactured by Kharazmi Co. versus originator brand (Trajenta) manufactured by Boehringer 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 (Volunteers), 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 a week. In the first round of the study, the candidates were divided into two groups the first group received a test tablet and the second group received 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. Sampling is 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 Linagliptin

Intervention groups

Intervention group 1: Trajenta 5mg tablet manufactured by Boehringer as a reference Intervention group 2: Linagliptin 5mg manufactured by Kharazmi Co. 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: **IRCT20200105046010N88**

Registration date: **2024-01-01, 1402/10/11**

Registration timing: **prospective**

Last update: **2024-01-01, 1402/10/11**

Update count: **0**

Registration date

2024-01-01, 1402/10/11

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

2024-01-05, 1402/10/15

Expected recruitment end date

2025-01-04, 1403/10/15

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Bioequivalence study of Linagliptin 5mg tablet manufactured by Kharazmi Co versus originator brand (Trajenta) manufactured by Boehringer in fasting condition in healthy volunteers

Public title

Bioequivalence study of Linagliptin 5mg tablet

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 Alcoholism and Narcoticism History of allergy to Linagliptin

Age

From **15 years** old to **55 years** old

Gender

Both

Phase

Bioequivalence

Groups that have been masked

- Participant

Sample size

Target sample size: **24**

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 (second 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 committee

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

2023-12-18, 1402/09/27

Ethics committee reference number

IR.TBZMED.REC.1402.691

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, 0.5, 0.75, 1, 1.5, 2, 2.5, 3, 4, 5, 6, 8, 10, 12, 48 and 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: Intervention group: single dose, one oral tablet Trajenta 5 mg manufactured by Boehringer as a reference product. after washout period, the volunteers receive Linagliptin 5 mg tablet manufactured by Kharazmi Co.

Category

Treatment - Drugs

2

Description

Intervention group: Single dose, one oral Linagliptin 5 mg tablet manufactured by Kharazmi company as test product. after washout period, the volunteers receive Trajenta 5 mg manufactured by Boehringer.

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

City

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

Tabriz University of Medical Sciences

Full name of responsible person

Peymn Tarrahomi

Street address

No. 115 Kharazmi Pharmacy Deadlock, Shahid Gholamreza Jalal St., Esteghlal Town

City

Tehran

Province

Tehran

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

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

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, Roshdieh

City

Tabriz

Province

East Azarbaijan

Postal code

5155935357

Phone

+98 41 3661 4125

Fax

Email

shokri.j@gmail.com

Person responsible for scientific inquiries

Contact

Name of organization / entity

Tabriz University of Medical Sciences

Full name of responsible person

Javad Shokri

Position

Professor

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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

Person responsible for updating data**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