Clinical Trial Protocol
Iranian Registry of Clinical Trials

30 Jun 2026

Bioequivalence study of Dapagliflozin 10 mg manufactured by Actover Co. versus originator brand in healthy volunteers in fasting condition

Protocol summary

Study aim
Bioequivalence Study of Dapagliflozin 10 mg manufactured by Actover Co. versus originator brand (Farxiga) manufactured by Astrazeneca company

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 Tabriz, in Radin laboratory in two (48h) periods. The interval between these two periods is a week. In the first round of the study, the candidates are divided into two groups and 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.

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, Alcoholism and Narcoticism, History of allergy to Dapagliflozin

Intervention groups
Intervention group 1: Farxiga 10 mg tablet as a reference
Intervention group 2: Dapagliflozin 10 mg manufactured by Actover 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: **IRCT20200623047902N37**
Registration date: **2024-01-26, 1402/11/06**
Registration timing: **prospective**

Last update: **2024-01-26, 1402/11/06**
Update count: **0**

Registration date
2024-01-26, 1402/11/06

Registrant information

Name
Elham Ghasemian

Name of organization / entity

Country
Iran (Islamic Republic of)

Phone
+98 21 6696 5196

Email address
ghasemian@zistdaru.ir

Recruitment status
Recruitment complete

Funding source

Expected recruitment start date
2024-02-20, 1402/12/01

Expected recruitment end date
2025-02-19, 1403/12/01

Actual recruitment start date
empty

Actual recruitment end date
empty

Trial completion date
empty

Scientific title
Bioequivalence study of Dapagliflozin 10 mg manufactured by Actover Co. versus originator brand in healthy volunteers in fasting condition

Public title

Bioequivalence study of Dapagliflozin 10 mg

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 Dapagliflozin

Age

From **18 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: Actover Co.'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

Research Ethics Committees of Tabriz University of Medical Sciences

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.1402.799

Health conditions studied

1

Description of health condition studied

This study is performed on healthy volunteers and drug concentration in whole blood is determined.

ICD-10 code

ICD-10 code description

Primary outcomes

1

Description

Drug concentration in blood

Timepoint

0, 0.5, 1, 1.5, 2, 2.5, 3, 3.5, 4, 6, 8, 10, 24, 48 h after drug administration

Method of measurement

Liquid chromatography-MASS-MASS (LC- Mas/Mas)

Secondary outcomes

1

Description

Time to reach maximum drug concentration in plasma

Timepoint

After intervention

Method of measurement

Time to reach the maximum drug concentration is recorded.

2

Description

Extent of drug 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 tablet Farxiga 10mg manufactured by Astrazaneca as a reference product. after the washout period, the volunteers receive dapagliflozin 10mg tablet manufactured by Actover Co.
Category
Treatment - Drugs

2

Description
Intervention group: Single dose, Dapagliflozin 10mg tablet manufactured by Actover Co. as a test product. after the washout period, the volunteers receive Farxiga 10 mg manufactured by Astrazeneca.
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
Province
East Azarbaijan
Postal code
5154995671
Phone
+98 914 313 5843
Email
shokri.j@gmail.com

Sponsors / Funding sources

1

Sponsor
Name of organization / entity
Actover Co.
Full name of responsible person
Reza Karimi
Street address
No. 58, 8th St, Gisha
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Province
Tehran
Postal code
1446863914
Phone
+98 26 3476 0314
Email
info@actoverco.com
Grant name
Grant code / Reference number
Is the source of funding the same sponsor organization/entity?
Yes
Title of funding source
Actover Co.
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
Islamic Azad University
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Elham Ghasemian
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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