Clinical Trial Protocol
Iranian Registry of Clinical Trials

10 Jun 2026

Comparative bioequivalence study of Dapagliflozin/ Metformin 5/ 1000 mg Tablet of ActoverCo. and Xigdue ® of Astera Zeneca as reference in 24 healthy male under fasting condition

Protocol summary

Study aim

This study will be performed to compare the pharmacokinetics and invivo parameters of Dapagliflozin/ Metformin 5/1000 mg Tablet formulation as a test product with Xigdue 5/1000 mg Tablet formulation as a reference product and to evaluate the bioequivalence of these two formulations.

Design

n-blinded, randomized, crossover in vivo bioequivalence study on 24 healthy males under fasting conditions. Block randomization for a treatment sequence of Test/Reference or Reference/Test is used.

Settings and conduct

In each period, volunteers will receive a single dose of the treatment in the Noor Research and Development Institute (Tarasht, Tehran). 2 dosing periods will be separated by a 7-day washout period.

Participants/Inclusion and exclusion criteria

Inclusion Criteria: Healthy subjects (male) between 20 – 45 years of age. Body Mass Index (BMI) within 15% of normal range according to the accepted normal values between 18.5 and 30(inclusive), calculated as kg/m2. Exclusion: Sensitivity to the pharmaceutical substance being studied. Cardiovascular, pulmonary, acute or chronic hormonal nervous system disease, gastrointestinal disease, and visual impairments on ophthalmology examinations.

Intervention groups

Intervention group 1: Dapagliflozin/ Metformin 5/ 1000 mg Tablet, produced by ActoverCo. is the test product. In each period, 12 of 24 subjects will be given a single oral dose of this product. Intervention group 2: Dapagliflozin/ Metformin 5/ 1000 mg Tablet (Xigdue®), produced by Astera Zeneca is the reference product. In each period, 12 of 24 subjects will be given a single oral dose of this product.

Main outcome variables

Peak Plasma Concentration

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20180620040164N76**
Registration date: **2025-01-08, 1403/10/19**
Registration timing: **prospective**

Last update: **2025-01-08, 1403/10/19**
Update count: **0**

Registration date

2025-01-08, 1403/10/19

Registrant information

Name
Behzad Montaha Sangari
Name of organization / entity
Noor research and educational institute (Tavan)
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Iran (Islamic Republic of)
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Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2025-01-31, 1403/11/12

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

Comparative bioequivalence study of Dapagliflozin/ Metformin 5/ 1000 mg Tablet of ActoverCo. and Xigdue ® of Astera Zeneca as reference in 24 healthy male under fasting condition

Public title

Comparative in vivo evaluation of 2 Dapagliflozin/ Metformin 5/ 1000 mg Tablet and Xigdue® 5/ 1000 mg Tablet formulations.

Purpose

Treatment

Inclusion/Exclusion criteria

Inclusion criteria:

Healthy subjects (male) between 20 – 45 years of age. Body Mass Index (BMI) within 15% of normal range according to the accepted normal values between 18.5 and 30(inclusive), calculated as kg/m2. Subjects with no significant diseases or abnormal findings during laboratory evaluations and clinical examination.Subjects with normal vital signs. Candidates must have normal vital signs. The consent of the candidates to all the requirements of the clinical study based on the instructions of the clinical study, which has been confirmed by accepting the informed consent form.

Exclusion criteria:

Sensitivity to the pharmaceutical substance being studied. Cardiovascular, pulmonary, acute or chronic hormonal nervous system disease, gastrointestinal disease, and visual impairments on ophthalmology examinations. A history of mental illness, water loss due to diarrhea or vomiting that lasts 24 hours before the medication is given. Systolic blood pressure greater than 130 or less than 100 mmHg. Diastolic blood pressure greater than 85 or less than 60 mmHg. Smokers who smoke more than 10 cigarettes a day and have problems with not smoking during each clinical study period. People who have used over the counter or doctor-prescribed medications 14 days before the start of the first period will need to take the medication at the same time during the study. People who have a history of alcoholism or alcohol consumption within the past 2 years. Volunteers who are heavy drinkers of caffeinated beverages, fruit juices (grapefruit juice) or follow a special diet (vegetarianism) or do heavy physical activity. A history of difficulty donating blood or donating more than 500 mL of blood less than seven days before the start of the study.

Age

From **20 years** old to **45 years** old

Gender

Male

Phase

Bioequivalence

Groups that have been masked

No information

Sample size

Target sample size: **24**

Randomization (investigator's opinion)

Randomized

Randomization description

The randomization schedule will be generated with https://www.sealedenvelope.com/simple-randomiser/v1/lists. A 2*2 block randomization list is created. We have 12 blocks and within each two volunteer numbers (allocated after screening) for all 24 volunteers. According to this list, a treatment sequence of Test/Reference or Reference/Test will be given to each volunteer.

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

Research Ethics committees of school of pharmacy and nursing Midwifery-Shahid Beheshti University of

Street address

Niayesh Highway, Valiasr Ave

City

Tehran

Province

Tehran

Postal code

1996835113

Approval date

2024-12-30, 1403/10/10

Ethics committee reference number

IR.SBMU.PHARMACY.REC.1403.236

Health conditions studied

1

Description of health condition studied

Diabetes mellitus due to underlying condition

ICD-10 code

E08

ICD-10 code description

Diabetes mellitus due to underlying condition

Primary outcomes

1

Description

Peak Plasma Concentration (Cmax)

Timepoint
14 blood samples will be withdrawn pre-dose and at 0.5, 1, 1.5, 2, 2.5, 3, 4, 5, 6, 8, 11, 24 and 48 hours after intervention.
Method of measurement
Using non-compartmental model of Win-Nonlin Professional software version 3.2.A (Pharsight Corporation, USA)

Secondary outcomes

1

Description
AUC (Area Under the Concentration-Time Curve)
Timepoint
14 blood samples will be withdrawn pre-dose and at 0.5, 1, 1.5, 2, 2.5, 3, 4, 5, 6, 8, 11, 24 and 48 hours after intervention.
Method of measurement
Using non-compartmental model of Win-Nonlin Professional software version 3.2.A (Pharsight Corporation, USA)

Intervention groups

1

Description
Intervention group 1: Dapagliflozin/ Metformin 5/ 1000 mg Tablet, produced by ActoverCo. is the test product. In each period, 12 of 24 subjects will be given a single oral dose of this product.
Category
Treatment - Drugs

2

Description
Intervention group 2: Dapagliflozin/ Metformin 5/ 1000 mg Tablet (Xigdue®), produced by Astera Zeneca is the reference product. In each period, 12 of 24 subjects will be given a single oral dose of this product.
Category
Treatment - Drugs

Recruitment centers

1

Recruitment center
Name of recruitment center
Noor Research & Development Institute (Tavan)
Full name of responsible person
Behzad Montaha Sangari
Street address
Sharif Innovation Station, North Habibollah Street, Hosseini Square, Teymoury Street, Tarasht.
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Sponsors / Funding sources

1

Sponsor
Name of organization / entity
Actover Pharmaceutical Co.
Full name of responsible person
Dr. Ramin Daneshmir
Street address
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Tehran
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1446863914
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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 Pharmaceutical 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
Noor Research & Development Institute
Full name of responsible person
Behzad Montaha sangari
Position
chief executive officer (CEO)
Latest degree
Medical doctor
Other areas of specialty/work
Medical Pharmacy
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Person responsible for scientific inquiries

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Person responsible for updating data

Contact

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Full name of responsible person
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Position
Chief executive officer (CEO)

Latest degree
Medical doctor

Other areas of specialty/work
Medical Pharmacy

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Behzad_first@yahoo.com

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
It's undetermind yet.

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