

Clinical Trial Protocol

Iranian Registry of Clinical Trials

27 Jul 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)

Country

Iran (Islamic Republic of)

Phone

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Email address

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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/lis>. 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, Teymouri Street, Tarasht.

City

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Province

Tehran

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1459926609

Phone

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Email

info@tavaninstitute.ir

Sponsors / Funding sources**1****Sponsor****Name of organization / entity**

Actover Pharmaceutical Co.

Full name of responsible person

Dr. Ramin Daneshmir

Street address

No. 58, 8th St., Gisha

City

Tehran

Province

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Postal code

1446863914

Phone

+98 21 4162 7000

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

Street address

Sharif innovation station, North Habibollah Street,

Hosseini Square, Teymouri Street, Tarasht.

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Person responsible for scientific inquiries

Contact

Name of organization / entity

Noor Research & Development Institute

Full name of responsible person

Seyed Mohsen Foroutan

Position

Principal investigator

Latest degree

Ph.D.

Other areas of specialty/work

Medical Pharmacy

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Person responsible for updating data

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

Street address

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Email

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 undetermined 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