Clinical Trial Protocol
Iranian Registry of Clinical Trials

27 Jul 2026

Comparative bioequivalence study of the Dapagliflozin 10 mg/ Metformin HCl 500 mg Extended-release tablets manufactured by Noavaran Daroui Kimia Company vs Xigduo® tablets manufactured by AstraZeneca Pharmaceutical Company in healthy volunteers

Protocol summary

Study aim
Examining the bioequivalence of domestically produced Dapagliflozin/Metformin tablet formulations with brand one named Xigduo®

Design
A cross over, not blinded, randomized, bioequivalence clinical trial on 24 healthy volunteers.

Settings and conduct
Study place: Applied Drug Research Center, Tabriz University of Medical Sciences. 24 healthy volunteers aged 18–50 years, with a body mass index (BMI) greater than 18 and less than 30, will be selected voluntarily through public announcements. Volunteers will take a single tablet in the fasting state and blood samples will be collected at 13 time points. One week later, the process is repeated for the brand medicine.

Participants/Inclusion and exclusion criteria
Inclusion criteria: the weight range of 60-100 kg; being non-smoker; being healthy in terms of physical examination, ECG and the laboratory tests; Volunteers who have agreed to an informed consent form. Exclusion criteria: History of allergic or adverse reaction to Dapagliflozin/Metformin or any similar product; blood pressure less than 90/60 mm Hg or higher than 140/90 mm Hg; Individuals who have donated whole blood during the previous 2 months of the study or donated blood components within 2 weeks before taking the first dose of the drug

Intervention groups
Intervention group 1: Dapagliflozin 10 mg/ Metformin 500 mg tablets by Noavaran Daroui Kimia Pharmaceutical Company is the test product. Intervention group 2: Xigduo® by AstraZeneca company is the reference product. In each period, 12 of 24 subjects will be given single dose of this product and for up to 48 hours, 3 ml of blood will be collected from the volunteer at 13 time points each time. After the washout period, the volunteers are placed in the opposite group

Main outcome variables
Plasma concentration of the drug

General information

Reason for update

Acronym

IRCT registration information
IRCT registration number: **IRCT20130313012810N55**
Registration date: **2025-03-29, 1404/01/09**
Registration timing: **prospective**

Last update: **2025-03-29, 1404/01/09**
Update count: **0**

Registration date
2025-03-29, 1404/01/09

Registrant information

Name
Hamed Hamishehkar

Name of organization / entity
Drug Applied Research Center, Tabriz University of Medical Sciences

Country
Iran (Islamic Republic of)

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+98 41 1336 3311

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Recruitment status
Recruitment complete

Funding source

Expected recruitment start date

2025-04-21, 1404/02/01

Expected recruitment end date

2025-04-25, 1404/02/05

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Comparative bioequivalence study of the Dapagliflozin 10 mg/ Metformin HCl 500 mg Extended-release tablets manufactured by Noavaran Daroui Kimia Company vs Xigduo® tablets manufactured by AstraZeneca Pharmaceutical Company in healthy volunteers

Public title

Dapagliflozin/Metformin tablet bioequivalence

Purpose

Treatment

Inclusion/Exclusion criteria

Inclusion criteria:

The weight range of participating candidates should be between 60-100 kg All candidates must be non-smokers Candidates should be healthy in terms of physical examination, ECG and the following laboratory tests: Hemoglobin, Hematocrit, Red and White Blood Count, MCV (Mean Body Volume), MCH (Mean Body Hemoglobin), Routine Urinalysis, Total Cholesterol, Triglyceride, Total Proteins, albumin, uric acid, total bilirubin, alkaline phosphatase, gamma glutamyl transpeptidase (γ-GT), aspartate aminotransferase (AST), alanine aminotransferase (ALT), urea, creatinine and fasting blood glucose. Volunteers who have agreed to an informed consent form. All candidates should not consume caffeine-containing drinks and chocolate during two days before the prescription, and this restriction must be followed until the last blood draw

Exclusion criteria:

History of allergic or adverse reaction to Dapagliflozin/Metformin or any similar product Volunteers with blood pressure less than 90/60 mm Hg or higher than 140/90 mm Hg Individuals who have donated whole blood during the last 2 months Individuals who have donated blood components, such as platelets, within the past 2 weeks

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**

Randomization (investigator's opinion)

Randomized

Randomization description

To randomly assign people in two groups, 24 cards with numbers 1 to 24 will be used in closed envelopes that are arranged irregularly. Each candidate will pick up an envelope after entering the study, and numbers 1-12 will be in group A and numbers 13-24 will be in group B. Group A will receive intervention 1 and group B will receive intervention 2, and after the first period, the interventions of the both groups will change for the second period

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

Ethics committee of Tabriz University of Medical Sciences

Street address

Tabriz University of Medical Sciences, Golgasht Street, Tabriz

City

Tabriz

Province

East Azarbaijan

Postal code

5166616471

Approval date

2025-03-10, 1403/12/20

Ethics committee reference number

IR.TBZMED.REC.1403.1091

Health conditions studied

1

Description of health condition studied

Bioequivalence study in healthy volunteers

ICD-10 code

ICD-10 code description

Primary outcomes

1

Description

Plasma concentration of the drug

Timepoint

13 sampling time included pre-dose (time 0) and at the following hours post-dose: 0.5, 1, 2, 3, 4, 5, 6, 8, 10, 12, 24, and 48 h

Method of measurement

Liquid Chromatography with tandem mass spectrometry (LC-MS-MS)

Secondary outcomes

empty

Intervention groups

1

Description
Intervention group 1: In this group, volunteers are given a single oral dose of the Dapagliflozin 10 mg/ Metformin 500 mg tablets manufactured by Noavaran Daroui Kimia Pharmaceutical Company. In each period, 12 of 24 subjects will be given single oral dose of this product. After the one week, the volunteers are placed in the Intervention group 2.
Category
Treatment - Drugs

2

Description
Intervention group 2: In this group, volunteers are given a single oral dose of the Dapagliflozin 10 mg/ Metformin 500 mg tablets manufactured by AstraZeneca Pharmaceutical Company. In each period, 12 of 24 subjects will be given single oral dose of this product. After the one week, the volunteers are placed in the Intervention group 1.
Category
Treatment - Drugs

Recruitment centers

1

Recruitment center
Name of recruitment center
Drug Applied Research Center, Tabriz University of Medical Sciences
Full name of responsible person
Hamed Hamishehkar
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Drug Applied Research Center, Tabriz University of Medical Sciences, Daneshgah Street,Tabriz
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Sponsors / Funding sources

1

Sponsor
Name of organization / entity
Noavaran Daroui Kimia
Full name of responsible person
Esmaeil Moazeni
Street address
Unit 4, No. 8, Hamedan St., North Kargar St., Tehran
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Tehran
Province
Tehran
Postal code
1439955991
Phone
+98 21 8801 2946
Email
info@kimia-pharma.co
Grant name
Grant code / Reference number
Is the source of funding the same sponsor organization/entity?
Yes
Title of funding source
Noavaran Daroui Kimia
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
Hamed Hamishehkar
Position
Professor
Latest degree
Ph.D.
Other areas of specialty/work
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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
Industry license will be required

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