Clinical Trial Protocol
Iranian Registry of Clinical Trials

10 Jun 2026

Comparative bioequivalence study of the Dapagliflozin 5 mg/ Metformin HCl 1000 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: Drug Applied Research Center affiliated to Tabriz University of Medical Science. The number of 24 volunteer in the age range of 18-50 years and the Body Mass Index range of 18-30, who are voluntarily selected through public notification. One tablet is taken fasting and blood is taken 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 60/90 mm Hg or higher than 90/140 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 5 mg/ Metformin 1000 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: **IRCT20130313012810N54**
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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Recruitment status
Recruitment complete

Funding source

Expected recruitment start date
2025-04-17, 1404/01/28

Expected recruitment end date
2025-04-20, 1404/01/31
Actual recruitment start date
empty
Actual recruitment end date
empty
Trial completion date
empty

Scientific title
Comparative bioequivalence study of the Dapagliflozin 5 mg/ Metformin HCl 1000 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 All candidates must be non-smokersCandidates 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 60/90 mm Hg or higher than 90/140 mm Hg Individuals who have donated whole blood during the last 2 months from the study Individuals who have donated donated blood components within 2 weeks before taking the first dose of the drug
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
Drug Applied Research Center, Tabriz University of Medical Sciences, Daneshgah Street,Tabriz
City
Tabriz
Province
East Azarbaijan
Postal code
51656-65811
Approval date
2025-03-10, 1403/12/20
Ethics committee reference number
IR.TBZMED.REC.1403.1092

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, which consists of 24 healthy and fasting volunteers, will receive a Dapagliflozin 5 mg/ Metformin 1000 mg tablet manufactured by Noavaran Daroui Kimia Pharmaceutical Company.
Category
Treatment - Drugs

2

Description
Intervention group 2, which consists of 24 healthy and fasting volunteers, will receive a Xigduo® tablet with a dose of Dapagliflozin 5/Metformin 1000 mg manufactured by AstraZeneca Pharmaceutical Company.
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
No. 1462, Jalal-Al-Ahmad Highway, Karghar Shomali
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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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Medical Pharmacy

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Sharing plan

Deidentified Individual Participant Data Set (IPD)
Undecided - It is not yet known if there will be a plan to make this available

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