

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)

Phone

+98 41 1336 3311

Email address

hamishehkar.hamed@gmail.com

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-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 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

AgeFrom **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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Email

hamishehkar.hamed@gmail.com

Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Noavaran Daroui Kimia

Full name of responsible person

Esmail Moazeni

Street address

No. 1462, Jalal-Al-Ahmad Highway, Karghar Shomali

City

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

Medical Pharmacy

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Person responsible for scientific inquiries

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Person responsible for updating data

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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