

Clinical Trial Protocol

Iranian Registry of Clinical Trials

09 Jun 2026

Comparative bioequivalence study of the Dapagliflozin 10-mg tablets manufactured by Noavaran Daroui Kimia Company

Protocol summary

Study aim

Examining the equivalency of domestically produced tablet formulations with brand samples

Design

Cross-over unblinded randomization

Settings and conduct

The number of 24 healthy volunteers in the age range of 18-60 years and the weight range of $18 < \text{BMI} < 30$, male, who are randomly and voluntarily selected through public notification. 1 tablet is taken fasting and blood is taken at 15 time points. A week later, the process is repeated for the external medicine.

Participants/Inclusion and exclusion criteria

Inclusion criteria: - The weight range of participating candidates should be between 60-100 kg. - All candidates must be non-smokers. - Candidates must 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 the informed consent form. Exit criteria: - History of allergic or adverse reaction to dapagliflozin or any similar product. - Volunteers with blood pressure less than 60/90 mm Hg or higher than 90/140 mm Hg. - smokers. - People who have taken medicine 10 days before the first day of use - Individuals who donated whole blood or blood components within 2 months prior to the first dose of the study product(s).

Intervention groups

After taking a tablet made by the internal production, 3 milliliters of blood will be collected from the volunteer in 15 time intervals for 48 hours. A week later, the process is repeated for a brand sample tablet. The drug concentration is measured in plasma.

Main outcome variables

Studying the Drug pharmacokinetic parameters

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20130313012810N5**

Registration date: **2022-12-25, 1401/10/04**

Registration timing: **registered_while_recruiting**

Last update: **2022-12-25, 1401/10/04**

Update count: **0**

Registration date

2022-12-25, 1401/10/04

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

2022-12-25, 1401/10/04

Expected recruitment end date

2022-12-29, 1401/10/08

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Comparative bioequivalence study of the Dapagliflozin 10-mg tablets manufactured by Noavaran Daroui Kimia Company

Public title

Comparative bioequivalence study of the Dapagliflozin 10-mg tablets manufactured by Noavaran Daroui Kimia Company

Purpose

Other

Inclusion/Exclusion criteria**Inclusion criteria:**

The weight range of participating candidates must be between 60-100 kg. All candidates must be non-smokers. The candidates must be healthy in terms of physical examination, ECG and the following laboratory tests: hemoglobin, hematocrit, red and white blood count, MCV (mean body mass), MCH (mean body hemoglobin), routine urinalysis, total cholesterol, triglycerides, total proteins, albumin, uric acid, total bilirubin, alkaline phosphatase, gamma glutamyl transpeptidase (γ -GT), amino aspartate transferase (AST), alanine aminotransferase (ALT), urea, creatinine and fasting blood glucose. Volunteers who agreed to the informed consent form.

Exclusion criteria:

History of allergic or adverse reaction to dapagliflozin or any similar product. Volunteers with blood pressure less than 60/90 mm Hg or higher than 90/140 mm Hg. Smokers. People who 10 days before the first day of consumption, Drug-experienced Individuals who donated whole blood or blood components within 2 months within 2 weeks prior to the first dose of the study product(s).

Age

From **18 years** old to **60 years** old

Gender

Male

Phase

Bioequivalence

Groups that have been masked

No information

Sample size

Target sample size: **24**

Randomization (investigator's opinion)

N/A

Randomization description**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

Daneshghah St. Drug Applied Research Center

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Tabriz

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East Azarbaijan

Postal code

51656-65811

Approval date

2022-09-19, 1401/06/28

Ethics committee reference number

IR.TBZMED.REC.1401.565

Health conditions studied**1****Description of health condition studied**

-

ICD-10 code

-

ICD-10 code description

-

Primary outcomes**1****Description**

Plasma concentration of the drug

Timepoint

15 sampling time till 48 h

Method of measurement

LCMSMS

Secondary outcomes

empty

Intervention groups**1****Description**

Intervention group: This study examines the bioequivalence of dapagliflozin produced by a domestic company with a foreign brand sample. We have only one intervention group and there is no control group. The intervention group, which includes healthy and fasting male volunteers, will receive a single dose of 10 mg

tablets manufactured by Noavaran Daroui Kimia pharmaceutical company or AstraZeneca brand in two 48-hour periods, on the first day of each period. And in 15 different time periods up to 48 hours after taking the drug, blood samples will be taken from the volunteers in the amount of 3 ml each time, that is, a total of 45 ml within 48 hours. The training that will be given to the volunteers includes avoiding the consumption of drinks containing alcohol and xanthine and other interfering drugs in the prescription drug from 48 hours before the start of the study until the end of the study. Also, on the first day of the study, after receiving the drug, the volunteers received a 20% glucose solution, so that after taking the pill, they will immediately take 240 cc of glucose solution, and after that, they should drink 60 cc of glucose solution every 15 minutes for 4 hours.

Category

N/A

Recruitment centers**1****Recruitment center****Name of recruitment center**

Drug Applied Research Center, Tabriz University of Medical Sciences

Full name of responsible person

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

KIMIA Noavaran Daroui

Full name of responsible person

Esmail Moazeni

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

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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

KIMIA Noavaran Daroui

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**Contact****Name of organization / entity**

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Position

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Full name of responsible person

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Position

Professor

Latest degree

Ph.D.

Other areas of specialty/work

Medical Pharmacy

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Drug Applied Research Center-Tabriz University of

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