Clinical Trial Protocol
Iranian Registry of Clinical Trials

16 Sep 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 < 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
City
Tabriz
Province
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

Hamed Hamishehkar

Street address

Drug Applied Research Center, Tabriz University of Medical Sciences

City

Tabriz

Province

East Azarbaijan

Postal code

51656-65811

Phone

+98 41 3336 3311

Email

hamishehkar.hamed@gmail.com

Sponsors / Funding sources

1

Sponsor

Name of organization / entity

KIMIA Noavaran Daroui

Full name of responsible person

Esmaeil 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

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

Street address

Daneshgah St. Drug Applied Research Center, Tabriz University of Medical Sciences

City

Tabriz

Province

East Azarbaijan

Postal code

51656-65811

Phone

+98 41 3336 3311

Email

hamishehkar.hamed@gmail.com

Person responsible for scientific 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

Street address
Drug Applied Research Center, Tabriz University of Medical Sciences
City
Tabriz
Province
East Azarbaijan
Postal code
51656-65811
Phone
+98 41 1336 3311
Fax
+98 41 1336 3311
Email
hamishehkar.hamed@gmail.com

Person responsible for updating data

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
Street address
Drug Applied Research Center-Tabriz University of Medical Science
City
Tabriz
Province
East Azarbaijan
Postal code
51656-65811
Phone
+98 41 3336 3181
Fax
Email
hamishehkar.hamed@gmail.com
Web page address

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