Clinical Trial Protocol
Iranian Registry of Clinical Trials

10 Jun 2026

Comparative bioequivalence study of the Dapagliflozin 10-mg tablets manufactured by Modava Company

Protocol summary

Study aim

Demonstration of bioequivalence of Dapagliflozin 10 mg tablets of Modava with Farxiga® tablet manufactured by AstraZeneca company after single dose administration

Design

Single dose, randomized and crossover bioequivalence study of Dapagliflozin 10mg tablets by Modava Company with Farxiga® (AstraZeneca Co.) in 24 healthy male volunteers in two groups. Lottery method with numbered envelopes was used for randomization.

Settings and conduct

Study place and the place for blood sample analysis are the Drug Applied Research Center affiliated to Tabriz University of Medical Science, respectively. 24 healthy male volunteers will receive one of the Dapagliflozin tablets test or reference in random sequence according to the randomization schedule. The washout period is 7 days, If the first sequence receives domestic medicine, they will receive brand medicine. Blood samples will be taken from all participants before and after receiving the drug at 0 (before dosing), 0.5, 0.75,1,1.5, 2, 2.5, 3, 4, 6, 8, 10,12, 24 and 48 after dosing.

Participants/Inclusion and exclusion criteria

Inclusion criteria: Healthy male subjects in the age range of 18-60 years and BMI (Body Mass Index) of 18-30; Exclusion criteria: Subjects with Blood Pressure ≤ 90/60 mm/Hg or BP ≥ 140/90 mm/Hg, Any evidence of impairment of renal, hepatic, cardiac, lung or gastrointestinal function or a history of tuberculosis, epilepsy, asthma, diabetes, psychosis or glaucoma and regular smoker.

Intervention groups

Intervention group1:Dapagliflozin 10 mg tablets by Modava is the test product. Intervention group 2:Farxiga® manufactured by AstraZeneca is the reference product. In each period, 12 of 24 subjects will be given single dose of this product.After the washout period, the volunteers are placed in the opposite group.

Main outcome variables

Peak Plasma Concentration (Cmax); Area under the concentration-time curve (AUC).

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20200407046981N45**
Registration date: **2022-10-19, 1401/07/27**
Registration timing: **prospective**

Last update: **2022-10-19, 1401/07/27**
Update count: **0**

Registration date

2022-10-19, 1401/07/27

Registrant information

Name

Fatima Molavi

Name of organization / entity

Country

Iran (Islamic Republic of)

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Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2022-12-22, 1401/10/01

Expected recruitment end date

2023-05-05, 1402/02/15

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 Modava Company

Public title
Study of absorption and elimination rate of Dapagliflozin 10-mg tablets in comparison with Dapagliflozin brand tablets (Farxiga®).

Purpose
Treatment

Inclusion/Exclusion criteria

Inclusion criteria:
The weight limit of each volunteer should be between 60 and 100 kg. All volunteers must be non-smokers. They must be healthy in terms of liver, kidney, respiratory system, mental and other general health characteristics that will be assessed. Candidates who have consented to the consent form.

Exclusion criteria:
Known hypersensitivity or idiosyncratic reaction to Dapagliflozin or any ingredients. Subjects with BP ≤ 90/60 mm/Hg or BP ≥ 140/90 mm/Hg. Taking any medicine during two week before dosing.

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)
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 Science

Street address
Third floor, central building No. 2, Golgasht street, Tabriz University of Medical Science, Tabriz, Iran

City
Tabriz

Province
East Azarbaijan

Postal code
5166614766

Approval date
2022-09-19, 1401/06/28

Ethics committee reference number
IR.TBZMED.REC.1401.566

Health conditions studied

1

Description of health condition studied
Bioequivalence study

ICD-10 code

ICD-10 code description

Primary outcomes

1

Description
Peak Plasma Concentration (Cmax)

Timepoint
0 (before dosing), 0.5, 0.75, 1, 1.5, 2, 2.5, 3, 4, 6, 8, 10, 12, 24 and 48 hours after dosing

Method of measurement
High-performance liquid chromatography—mass spectrometry (HPLC-MS)

Secondary outcomes

1

Description
AUC (Area Under the Concentration-Time Curve)

Timepoint
0 (before dosing) 0.5, 0.75, 1, 1.5, 2, 2.5, 3, 4, 6, 8, 10, 12, 24 and 48 hours after dosing

Method of measurement
Using non-compartmental model of Win-Nonlin Professional software version 3.2.A (Pharsight Corporation, USA) or SPSS

Intervention groups

1

Description
Intervention group 1: In this group, volunteers are given a single oral dose of Dapagliflozin 10 mg tablets produced by Modava Co. (Domestic). In each period, 12 of 24 subjects will be given single oral dose of this product. After the washout period, 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 Dapagliflozin 10 mg tablets (Farxiga®), produced by Pfizer Company (Brand). In each period, 12 of 24 subjects will be given single oral dose of this product. After the washout period, 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

Full name of responsible person
Hamed Hamishehkar

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Drug Applied Research Center, In front of Shahid Madani Hospital, Daneshghah Blvd, Tabriz, Iran

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Sponsors / Funding sources

1

Sponsor

Name of organization / entity
Modava pharmaceutical company

Full name of responsible person
Farrokh Rahimzadeh

Street address
Unit.5, No. 275, Shahid Beheshti St., Modava Pharmacy

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Tehran

Province
Tehran

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1514617714

Phone
+98 21 8817 4996

Email
r.otadi@modavaco.com

Web page address
http://www.modavapharma.com/

Grant name

Grant code / Reference number

Is the source of funding the same sponsor organization/entity?
Yes

Title of funding source
Modava pharmaceutical company

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
Fatima Molavi

Position
Non-Faculty Academic Position

Latest degree
Ph.D.

Other areas of specialty/work
Pharmaceutics

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Person responsible for scientific inquiries

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Position

Professor

Latest degree

Ph.D.

Other areas of specialty/work

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Person responsible for updating data

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Position

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Latest degree

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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

There is no further information

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

Undecided - It is not yet known if there will be a plan to make this available

Analytic Code

Not applicable

Data Dictionary

Undecided - It is not yet known if there will be a plan to make this available