

# 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  $\leq$  90/60 mm/Hg or BP  $\geq$  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)

##### Phone

+98 41 3336 2700

##### Email address

molavif@tbzmed.ac.ir

##### 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  $\leq$  90/60 mm/Hg or BP  $\geq$  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

##### Street address

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

##### City

Tabriz

##### Province

East Azarbaijan

##### Postal code

5165665811

##### Phone

+98 41 3336 7914

##### Fax

+98 41 3336 7914

##### Email

Hamishehkar.hamed@gmail.com

## 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

##### City

Tehran

##### Province

Tehran

##### Postal code

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

##### Street address

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

##### City

Tabriz

##### Province

East Azarbaijan

##### Postal code

5165665811

##### Phone

+98 41 3336 7914

##### Email

F.molavi85@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**  
Pharmaceutics  
**Street address**  
Drug Applied Research Center, In front of Shahid  
Madani Hospital, Daneshghah Blvd, Tabriz, Iran  
**City**  
Tabriz  
**Province**  
East Azarbaijan  
**Postal code**  
5165665811  
**Phone**  
+98 41 3336 7914  
**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**  
Fatima Molavi  
**Position**  
Non-Faculty Academic Position  
**Latest degree**  
Ph.D.  
**Other areas of specialty/work**

Pharmaceutics  
**Street address**  
ایران، تبریز، خیابان دانشگاه، روبروی بیمارستان شهید مدنی،  
مجتمع تحقیق و توسعه دانشگاه علوم پزشکی تبریز، مرکز  
تحقیقات کاربردی دارویی  
**City**  
Tabriz  
**Province**  
East Azarbaijan  
**Postal code**  
5165665811  
**Phone**  
+98 41 3336 7914  
**Email**  
F.molavi85@gmail.com

## 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