

Clinical Trial Protocol

Iranian Registry of Clinical Trials

17 Sep 2026

In- Vivo Bioequivalence study of Daclaasvir/Sofosbuvir 60/400 mg Actero Middle East Pharma (DATEX 400/60 mg Tab.) with brand drug (Sofosbuvir/Daclatasivir® 400/60 mg, Mylan, Germany) in Iranian healthy volunteers.

Protocol summary

Study aim

In- Vivo Bioequivalence study of Daclaasvir/Sofosbuvir 60/400 mg Actero Middle East Pharma (DATEX 400/60 mg Tab.) with brand drug (Sofosbuvir/Daclatasivir® 400/60 mg, Mylan, Germany) in Iranian healthy volunteers.

Design

In-vivo bioequivalence study, single-blind, cross-over with one week wash-out time, two intervention groups, randomized with paper lottery randomization method.

Settings and conduct

This study is carried out in Simin Baspar Tayf-Gostar Company, Tabriz, Iran. The study population is 24 healthy Iranian volunteers. This study is a single-blind study and by taking out the drugs from the original packaging, the volunteers will not know the time of receiving the test drug and the brand. This study is a cross over study that is performed in two time periods of 48 hours with a two-week wash-out period.

Participants/Inclusion and exclusion criteria

Inclusion criteria: age between 18-55 years old; body mass index (BMI) in the range of 18-28. Exclusion criteria: history of heart, kidney and liver disease; pregnancy; drug addiction; smoking

Intervention groups

Intervention group 1: Single dose Daclaasvir/Sofosbuvir 60/400 mg Actero Middle East Pharma. Intervention group 2: brand drugs (Sofosbuvir/Daclatasivir® 400/60 mg, Mylan, Germany)

Main outcome variables

Plasma drug concentration

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20200105046010N68**

Registration date: **2022-09-05, 1401/06/14**

Registration timing: **registered_while_recruiting**

Last update: **2022-09-05, 1401/06/14**

Update count: **0**

Registration date

2022-09-05, 1401/06/14

Registrant information

Name

Javad Shokri

Name of organization / entity

Country

Iran (Islamic Republic of)

Phone

+98 41 3661 4125

Email address

shokri.j@gmail.com

Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2022-09-03, 1401/06/12

Expected recruitment end date

2023-05-02, 1402/02/12

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

In- Vivo Bioequivalence study of Daclaasvir/Sofosbuvir

60/400 mg Actero Middle East Pharma (DATEX 400/60 mg Tab.) with brand drug (Sofosbuvir/Daclatasivir® 400/60 mg, Mylan, Germany) in Iranian healthy volunteers.

Public title

In-vivo Bioequivalence Test of Daclaasvir/Sofosbuvir 60/400 mg Actero Middle East with brand drug (Sofosbuvir/Daclatasivir® 400/60 mg, Mylan, Germany)

Purpose

Treatment

Inclusion/Exclusion criteria

Inclusion criteria:

General health Body mass index between 18-28 Informed consent Being at the age of 18-55 years old

Exclusion criteria:

Smoking A history of cardiovascular disease A history of liver & kidney disease Pregnancy Alcohol & Drug addiction Hypersensitivity to the drug

Age

From **18 years** old to **55 years** old

Gender

Both

Phase

Bioequivalence

Groups that have been masked

- Participant

Sample size

Target sample size: **24**

Randomization (investigator's opinion)

Randomized

Randomization description

For this purpose, A 24- persons group will be selected and divided to two 12-persons groups randomly. The names of all volunteers will be written on paper pieces and wrapped in aluminum foils. The first 12 papers will randomly be withdrawn from bottle will be selected as group A and others will be categorized in group B.

Blinding (investigator's opinion)

Single blinded

Blinding description

Candidates are not aware of receiving the test drug or brand one. In a one-blind study, information that could distort the test result is hidden from the candidates, but the person in charge of the test is aware of it. Test and Brand drugs are removed from their packaging by the executor and placed in similar and coded cans. Volunteers will not be informed about receiving the brand or test drug.

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

Third floor; Central building; Tabriz University of Medical Sciences; Dneshgah St.

City

Tabriz

Province

East Azarbaijan

Postal code

5166614766

Approval date

2021-11-15, 1400/08/24

Ethics committee reference number

IR.TBZMED.REC.1400.736

Health conditions studied

1

Description of health condition studied

Bio equivalence test

ICD-10 code

ICD-10 code description

Primary outcomes

1

Description

Plasma drug concentration

Timepoint

Sampling times in this study will be , 0.25, 0.5, 0.75, 1, 1.25, 1.5, 1.75, 2, 2.5, 3, 4, 6, 8, 10, 24 48 hours after prescribing the tablet.

Method of measurement

High Performance Liquid Chromatography with tandem mass spectroscopy detector

Secondary outcomes

empty

Intervention groups

1

Description

Intervention group 1: One test tablet (Daclaasvir/Sofosbuvir 60/400 mg produced by Actero Middle East Pharma) will be received. Blood samples will be taken for 72 hours at the mentioned times after drug administration and the concentration of the drug in Plasma samples will be measured by liquid chromatography with mass spectroscopy detector

Category

Treatment - Other

2

Description

Intervention group 2: One Reference tablet Sofosbovir/Daclatasivir® 400/60 mg, Mylan, Germany will be received. Blood samples will be taken for 72 hours at the mentioned times after drug administration and the concentration of drug in plasma samples will be measured by liquid chromatography with mass spectroscopy detector.

Category

Treatment - Other

Recruitment centers

1

Recruitment center

Name of recruitment center

Simin Baspar Teyf Gostar Company

Full name of responsible person

Javad Shokri

Street address

No.48, Ferdos square

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Tabriz

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Postal code

5167874434

Phone

+98 41 3384 2724

Email

Shokri.j@gmail.com

Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Actero middle east Pharm Co.

Full name of responsible person

Sanaz Golbabaie

Street address

No 58, 6th St, Balouchestan St, Tehran, Iran

City

Tehran

Province

East Azarbaijan

Postal code

1446863914

Phone

+98 21 4431 9003

Email

info@actoverco.com

Grant name

Grant code / Reference number

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

Yes

Title of funding source

Actero middle east Pharm Co.

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

Persons

Person responsible for general inquiries

Contact

Name of organization / entity

Dariush Omidfar

Full name of responsible person

Simin Baspar Teyf Gostar Company

Position

Lab. Manager

Latest degree

Master

Other areas of specialty/work

Bioanalysis

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Person responsible for scientific inquiries

Contact

Name of organization / entity

Tabriz University of Medical Sciences

Full name of responsible person

Javad Shokri

Position

Professor

Latest degree

Ph.D.

Other areas of specialty/work

Medical Pharmacy

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Person responsible for updating data

Contact

Name of organization / entity
Simin Baspar Teyf Gostar Company
Full name of responsible person
Ahad Sheikhloo
Position
Official Manager
Latest degree
Master
Other areas of specialty/work
Official Manager
Street address
No.48, Ferdos square
City
Tabriz
Province
East Azarbaijan
Postal code

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

All information and data of the study will remain secured based on the agreement established between researcher and drug producer.

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

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