Clinical Trial Protocol
Iranian Registry of Clinical Trials

09 Nov 2026

In- Vivo Bioequivalence study of Daclaasvir/Sofosbuvir 60/400 mg Actero Middle East Pharma (DATEX 400/60 mg Tab.) with brand drug (Sofosbovir/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 (Sofosbovir/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 singl- 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 Actro Middle East Pharma. Intervention group 2: brand drugs (Sofosbovir/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 (Sofosbovir/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 (Sofosbovir/Daclatasivir® 400/60 mg, Mylan, Germany)
Purpose
Treatment
Inclusion/Exclusion criteria
Inclusion criteria:
General health Body mass index between18-28 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 Actro 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
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No.48, Ferdos square
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Sponsors / Funding sources

1

Sponsor
Name of organization / entity
Actero middle east Pharm Co.
Full name of responsible person
Sanaz Golbabaei
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No 58, 6th St, Balouchestan St, Tehran, Iran
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1446863914
Phone
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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
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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
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