Clinical Trial Protocol
Iranian Registry of Clinical Trials

05 Nov 2026

A study to compare the relative bioavailability of Aburaihan and Gilead formulations of ledipasvir/sofosbuvir 90/400 mg tablets in 24 healthy adult volunteers under fasting conditions

Protocol summary

Study aim
The study aims to evaluate the bioequivalence of ledipasvir/sofosbuvir 90/400 mg tablets produced by two different pharmaceutical companies under fasting conditions

Design
This randomized, single-dose, two-way, crossover study is conducted to compare the pharmacokinetics of ledipasvir/sofosbuvir and Harvoni® tablets in 24 healthy adult volunteers. Volunteers will be sorted and receive a number from 1 to 24. In the first phase of the study, 12 volunteers will receive ledipasvir/sofosbuvir manufactured by Aburaihan and the remaining 12 volunteers will receive Harvoni® produced by Gilead company. The administered drugs will be replaced to another group in the second phase of the study.

Settings and conduct
The dose administration and subsequent sample collection will be performed in Motahhari hospital (Gonbade Kavous, Iran).

Participants/Inclusion and exclusion criteria
Inclusion criteria: aged 18-55 years; subject available for the entire study period; willingness to adhere to protocol requirements as evidenced by written informed consent; good health at screening. Exclusion criteria: History of use of any drug; hypersensitivity or intolerance; significant history or current evidence of chronic disease; receipt of any drug as part of a research study within 30 days prior to the present study.

Intervention groups
First intervention group: A single ledipasvir/sofosbuvir 90/400 mg tablet manufactured by Aburaihan company to 12 subjects. Second intervention group: A single 90/400 oral dose of Harvoni® manufactured by Gilead company to 12 subjects. Since in this study, the volunteers will receive both test and reference drugs, each volunteer will act as his own control.

Main outcome variables
Drug plasma concentration; Area under the plasma concentration-time curve

General information

Reason for update
Acronym
IRCT registration information
IRCT registration number: **IRCT20130626013776N65**
Registration date: **2022-01-12, 1400/10/22**
Registration timing: **prospective**

Last update: **2022-01-12, 1400/10/22**
Update count: **0**

Registration date
2022-01-12, 1400/10/22

Registrant information
Name
Hossein Amini
Name of organization / entity
Golestan University of Medical Sciences
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Recruitment status
Recruitment complete
Funding source

Expected recruitment start date
2022-03-21, 1401/01/01
Expected recruitment end date
2023-03-21, 1402/01/01
Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

A study to compare the relative bioavailability of Aburaihan and Gilead formulations of ledipasvir/sofosbuvir 90/400 mg tablets in 24 healthy adult volunteers under fasting conditions

Public title

Bioequivalence study of ledipasvir/sofosbuvir 90/400 mg tablets

Purpose

Basic scienece

Inclusion/Exclusion criteria

Inclusion criteria:

18-55 years of age. The subject is able and willing to provide signed informed consent. The subject is available for the entire study period. Willing to adhere to protocol requirements as evidenced by written informed consent. The subject has a stable residence and telephone. Good health as determined by lack of clinically significant abnormalities in health assessments performed at screening.

Exclusion criteria:

History of allergy or sensitivity to ledipasvir and sofosbuvir. History of any drug hypersensitivity or intolerance which, in the opinion of the investigator, would compromise the safety of the subject of the study. Significant history or current evidence of chronic infectious disease, system disorder or organ dysfunction. Presence of gastrointestinal disease or history of malabsorption within the last year. History of a medical disorders occurring within the last year that required hospitalization or medication. Use of pharmacologic agents known to significantly induce or inhibit drug-metabolizing enzymes within 30 days prior to dosing. Receipt of any drug as part of a research study within 30 days prior to the present study. Donation or significant loss of whole blood (480 ml or more) within 30 days prior to the present study.

Age

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

Gender

Both

Phase

Bioequivalence

Groups that have been masked

No information

Sample size

Target sample size: **24**

More than 1 sample in each individual

Number of samples in each individual: **2**

In a crossover design, each person is its own control and receives two different interventions

Randomization (investigator's opinion)

Randomized

Randomization description

A pot randomization method will be used in this study. 12 papers are labeled "Reference Product" and 12 papers are written as "Test Product". The papers are then placed in sealed envelopes, and participants randomly select a paper and will be placed in the Reference or Test groups.

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 Golestan University of Medical Sciences

Street address

Falsafi Building, Sari Road Km 2

City

Gorgan

Province

Golestan

Postal code

4934174515

Approval date

2021-11-14, 1400/08/23

Ethics committee reference number

IR.GOUMS.REC.1400.292

Health conditions studied

1

Description of health condition studied

.

ICD-10 code

ICD-10 code description

Primary outcomes

1

Description

Drug plasma concentration

Timepoint

At time zero and 0.25, 0.5, 0.75, 1, 1.5, 2, 2.5, 3, 3.5, 4, 5, 6, 8, 10, 24, 48 and 72 h after drug administration

Method of measurement

Blood sampling and measurement of drug concentrations by high-performance liquid chromatography

2

Description
Area under plasma concentration-time curve
Timepoint
At time zero and 0.25, 0.5, 0.75, 1, 1.5, 2, 2.5, 3, 3.5, 4, 5, 6, 8, 10, 24, 48 and 72 h after drug administration
Method of measurement
Blood sampling and measurement of drug concentrations by high-performance liquid chromatography

Secondary outcomes

1

Description
Plasma half-life
Timepoint
From the terminal 60 hours of plasma concentration-time profile
Method of measurement
Blood sampling and drug analysis by high-performance liquid chromatography method

Intervention groups

1

Description
Intervention group: Oral administration of a single dose of ledipasvir/sofosbuvir manufactured by Aburaihan to healthy volunteers under fasting condition in the morning of the experiment day
Category
Treatment - Drugs

2

Description
Intervention group: Oral administration of a single dose of Harvoni manufactured by Gilead to healthy volunteers under fasting condition in the morning of the experiment day
Category
Treatment - Drugs

Recruitment centers

1

Recruitment center
Name of recruitment center
Dialysis Center, S. Motahhari Hospital
Full name of responsible person
Yahya Naserifard
Street address
Taleghani Street
City
Gonbade Kavous
Province
Golestan
Postal code
4916817693
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+98 17 3252 5972
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+98 17 3252 5972
Email
haminhplc@yahoo.com

Sponsors / Funding sources

1

Sponsor
Name of organization / entity
Aburaihan Pharmaceuticals
Full name of responsible person
Dr. Kobra Mosavi
Street address
Head Office: No.1، khoshvaght st.,Tehranpars Intersection
City
Tehran
Province
Tehran
Postal code
1654613111
Phone
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Fax
+98 21 7770 7176
Email
clinical.studies@aburaihan.com
Web page address
http://aburaihan.com
Grant name
Bioequivalence Study
Grant code / Reference number
Is the source of funding the same sponsor organization/entity?
No
Title of funding source
Aburaihan Pharmaceuticals
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
Gorgan University of Medical Sciences
Full name of responsible person
Hossein Amini
Position

Associate professor

Latest degree

Ph.D.

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

Data are confidential and need permission from the company.

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