Clinical Trial Protocol
Iranian Registry of Clinical Trials

09 Jun 2026

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

Protocol summary

Summary

This randomized, single-dose, two-way, crossover study is conducted to compare the relative bioavailability of two formulations of ledipasvir/sofosbuvir tablets under fasting conditions in 24 healthy adults male volunteers. In each study period, a single 90/400 mg dose is administered to the subjects following an overnight fast of at least 10 hours. The test formulation is ledipasvir/sofosbuvir 90/400 mg tablets manufactured by Sobhan Medicine Trade Development (SMTD) Company and the reference formulation is HARVONI® (ledipasvir/sofosbuvir) 90/400 mg tablet manufactured by Gilead. The subjects will receive the test products and the reference product in two periods; the order of administration will be according to the dosing randomization schedule. There will be a 7-day interval between treatments. Venous blood (3 ml) for the determination of ledipasvir (LP), sofosbuvir (SF) and the metabolite of SF in plasma is sampled before dosing and at 0.25, 0.5, 0.7, 1, 1.5, 2, 2.5, 3, 3.5, 4, 5, 6, 8, 10, 24, 48, and 72 hours after dosing (a total of 17 samples per profile). Criteria for the evaluation include the time course of the plasma concentrations of LP, SF and SF metabolite over the 72 h after the administration of the products as summarized by the area under the curve from time zero to infinity (AUC0-inf), the maximum plasma concentration (Cmax), time to reach Cmax (Tmax) and plasma half-life (t1/2). Statistical analysis is performed to evaluate the relative bioavailability of the test formulation to that of the reference product.

General information

Acronym

IRCT registration information

IRCT registration number: **IRCT2017022213776N4**
Registration date: **2017-03-07, 1395/12/17**
Registration timing: **prospective**

Last update:
Update count: **0**

Registration date

2017-03-07, 1395/12/17

Registrant information

Name
Hossein Amini
Name of organization / entity
Golestan University of Medical Sciences
Country
Iran (Islamic Republic of)
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+98 17 1442 1651
Email address
hamini@sbmu.ac.ir

Recruitment status

Recruitment complete

Funding source

Sobhan Medicine Trade Development Company

Expected recruitment start date

2017-04-01, 1396/01/12

Expected recruitment end date

2017-10-01, 1396/07/09

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

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

fasting conditions

Public title
Bioequivalence study of ledipasvir/sofosbuvir 90/400 mg tablets under fasting conditions
Purpose
Health service research
Inclusion/Exclusion criteria
Inclusion criteria: 1. Males, 18-50 years of age (inclusive). 2. The subject is able and willing to provide written informed consent. 3. The subject is available for the entire study period and is willing to adhere to protocol requirements as evidenced by written informed consent. 4. The subject has stable residence and telephone. 5. Good health as determined by lack of clinically significant abnormalities in health assessments performed at screening. Exclusion criteria: 1. History of allergy or sensitivity to ledipasvir/sofosbuvir, or history of any drug hypersensitivity or intolerance which, in the opinion of the investigator, would compromise the safety of the subject or the study. 2. Significant history or current evidence of chronic infectious disease, system disorder or organ dysfunction. 3. Presence of gastrointestinal disease or history of malabsorption within the last year. 4. Presence of a medical condition requiring regular treatment with prescription drugs. 5. Use of pharmacologic agents known to significantly induce or inhibit drug-metabolizing enzymes within 30 days prior to dosing. 6. Receipt of any drug as part of a research study within 30 days prior to dosing. 7. Donation or significant loss of whole blood (480 ml or more) within 30 days prior to dosing.
Age
From **18 years** old to **50 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
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
Golestan University of Medical Sciences
Street address
Km 2 Sari Road Gorgan
City
Gorgan
Postal code
Approval date
2017-01-15, 1395/10/26
Ethics committee reference number
ir.goums.rec.1395.229

Health conditions studied

1

Description of health condition studied
Healthy volunteers
ICD-10 code
Y41.5
ICD-10 code description
Antiviral drugs

Primary outcomes

1

Description
Maximum plasma concentration (Cmax)
Timepoint
After intervention
Method of measurement
Blood sampling

2

Description
Area-under the curve (AUC) for plasma concentrations
Timepoint
After intervention
Method of measurement
Blood sampling

Secondary outcomes

1

Description
Time to reach Cmax (Tmax)
Timepoint
After intervention
Method of measurement
Blood sampling

Intervention groups

1

Description

Single dose ofone ledipasvir/sofosbuvir 90/400 mg tablets manufactured by Sobhan Medicine Trade Development Company

Category

Treatment - Drugs

2

Description

Single dose of one Harvoni (ledipasvir/sofosbuvir) 90/400 mg tablets manufactured by Gilead

Category

Treatment - Drugs

Recruitment centers

1

Recruitment center

Name of recruitment center

Dialysis Center

Full name of responsible person

Mr. Ghezelsefloo

Street address

Taleghani Street, Shaheed Motahhari Hospital

City

Gonbad-Kavous

Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Sobhan Medicine Trade Development Company

Full name of responsible person

Mrs. Parhoon

Street address

Central Office, Yosef Abad

City

Tehran

Grant name

Grant code / Reference number

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

Yes

Title of funding source

Sobhan Medicine Trade Development Company

Proportion provided by this source

100

Public or private sector

empty

Domestic or foreign origin

empty

Category of foreign source of funding

empty

Country of origin

Type of organization providing the funding

empty

Person responsible for general inquiries

Contact

Name of organization / entity

Gorgan Bioanalysis Center

Full name of responsible person

Dr. Hossein Amini

Position

Head of Center

Other areas of specialty/work

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Dr. Hossein Amini

Position

Associtate Professor, Ph.D

Other areas of specialty/work

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University Main Campus

City

Gorgan

Postal code

Phone

00

Fax

Email

Web page address

Sharing plan

Deidentified Individual Participant Data Set (IPD)

empty

Study Protocol

empty

Statistical Analysis Plan

empty

Informed Consent Form

empty

Clinical Study Report

empty

Analytic Code

empty

Data Dictionary

empty