

# 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 (AUC<sub>0-inf</sub>), the maximum plasma concentration (C<sub>max</sub>), time to reach C<sub>max</sub> (T<sub>max</sub>) and plasma half-life (t<sub>1/2</sub>). 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)

###### Phone

+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 of one 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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## **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*