

# Clinical Trial Protocol

## Iranian Registry of Clinical Trials

04 Jul 2026

### **In- Vivo Bioequivalence study of Tenofovir Alafenamide tablets 25 mg (Sobhan Trade Co, Iran) with brand drug (Vemlidy® 25 mg, Gilead, Canada) in Iranian healthy volunteers.**

#### **Protocol summary**

##### **Study aim**

In- Vivo Bioequivalence study of Tenofovir Alafenamide tablets 25 mg (Sobhan Trade Co, Iran) with brand drug (Vemlidy® 25 mg, Gilead, Canada) in Iranian healthy volunteers.

##### **Design**

In-vivo bioequivalence study of ETenofovir Alafenamide tablets 25 mg produced by Sobhan Trade Pharma in compared with reference drug (Vemlidy® 25 mg, Gilead, Canada). The single blind, Cross-over, two period, two groups (Intervention and control) and randomized (paper lottery randomization method) study with one week wash-out time.

##### **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 existing 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 72 hours with a two-week wash-out period.

##### **Participants/Inclusion and exclusion criteria**

Inclusion criteria: Age between 18-55 years, 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: Single dose Tenofovir Alafenamide tablets 25 mg produced by Sobhan Trade Pharma.  
Control group: brand drugs (Vemlidy® 25 mg, Gilead, Canada)

##### **Main outcome variables**

Plasma drug concentration

#### **General information**

##### **Reason for update**

##### **Acronym**

##### **IRCT registration information**

IRCT registration number: **IRCT20200105046010N52**

Registration date: **2022-01-03, 1400/10/13**

Registration timing: **registered\_while\_recruiting**

Last update: **2022-01-03, 1400/10/13**

Update count: **0**

##### **Registration date**

2022-01-03, 1400/10/13

##### **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**

2021-12-29, 1400/10/08

##### **Expected recruitment end date**

2022-06-29, 1401/04/08

##### **Actual recruitment start date**

empty

##### **Actual recruitment end date**

empty

##### **Trial completion date**

empty

## Scientific title

In- Vivo Bioequivalence study of Tenofovir Alafenamide tablets 25 mg (Sobhan Trade Co, Iran) with brand drug (Vemlidy® 25 mg, Gilead, Canada) in Iranian healthy volunteers.

## Public title

In-vivo Bioequivalence Test of Tenofovir Alafenamide tablets with brand drug (Vemlidy® 25 mg, Gilead, Canada)

## 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

Parallel

## 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.1400.735

## 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, 0:15, 0:30, 0:45, 1, 1:15, 1:30, 2:00, 2:30, 3, 4, 6, 8, 10, 24 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: One test tablet (Tenofovir Alafenamide tablets 25 mg produced by Sobhan Trade Pharma.) will be received. Blood samples will be taken for 24 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

Control group: One Reference tablet (Vemlidy® 25 mg, Gilead, Canada) will be received. Blood samples will be taken for 24 hours at the mentioned times after drug administration and the concentration of Tenofovir Alafenamide 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

##### City

Tabriz

##### Province

East Azarbaijan

##### Postal code

5167874434

##### Phone

+98 41 3384 2724

##### Email

Shokri.j@gmail.com

### Sponsors / Funding sources

1

#### Sponsor

##### Name of organization / entity

Sobhan Trade Pharmaceutical Company

##### Full name of responsible person

Samira Parhon

##### Street address

Beheshti St Sabounchi St No11 Unit 2

##### City

Tehran

##### Province

Tehran

##### Postal code

88632457

##### Phone

+98 21 8863 2754

##### Email

info@smttd.ir

##### Grant name

##### Grant code / Reference number

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

Yes

#### Title of funding source

Sobhan Trade Pharmaceutical Company

#### 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

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

##### Street address

Faculty of Pharmacy, Tabriz University of Medical Sciences, Daneshgah

##### City

Tabriz

##### Province

East Azarbaijan

##### Postal code

5166414766

##### Phone

+98 41 3334 8489

##### Email

Shokri.j@gmail.com

### 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.

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Medical Pharmacy

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**Postal code**  
5166414766  
**Phone**  
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**Email**  
Shokri.j@gmail.com

## Person responsible for updating data

### Contact

**Name of organization / entity**  
Simin Baspar Teyf Gostar Company  
**Full name of responsible person**  
Dariush Omidar  
**Position**  
Lab. Manager  
**Latest degree**  
Master  
**Other areas of specialty/work**  
Others  
**Street address**  
No.48, Ferdos square  
**City**  
Tabriz  
**Province**  
East Azarbaijan  
**Postal code**  
5167874434  
**Phone**  
+98 41 3384 2724  
**Email**  
Dariush.omidfar@gmail.com

## 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

Yes - There is a plan to make this available

### Title and more details about the data/document

Only protocol and methods of study are sharable

### When the data will become available and for how long

The access to data will be possible after finishing of project (almost 6 months after receiving of IRCT Code).

### To whom data/document is available

Pharmaceutical and medical sciences researchers

### Under which criteria data/document could be used

Projects information's for any publications is not allowed.

### From where data/document is obtainable

By email to the project manager (shokri.j@gmail.com)

### What processes are involved for a request to access data/document

These information are confidential and be under disposal of the project's contractor. Upon request, the information will be accessed to the applicant by the Executor's email after receiving contractor's consent.

### Comments