Clinical Trial Protocol
Iranian Registry of Clinical Trials

17 Sep 2026

In vivo bioequivalence study of Sofosbuvir/Daclatasvir (400/60) manufactured by Bakhtar Bioshimi Co. compared with innovator product

Protocol summary

Study aim

In vivo fasted-state bioequivalence study of Sofosbuvir/Daclatasvir tablet

Design

The clinical trial has control and test groups with crossover, randomized design, without blinding. Twenty-four healthy male volunteers will participate randomly in the study as two twelve-person study groups. Each volunteer will receive a single dose of drug in two periods. In one period the test formulation and in another period the reference formulation. Therefore, each volunteer will be his own "Control". To randomly assign participants in two groups, the lottery method will be used.

Settings and conduct

After oral administration of one Sofosbuvir 400/Daclatasvir 60 tablet, the blood samples will be collected in predetermined time intervals up to 72 hours. The samples will be stored in freezer -4 degrees centigrade until analysis. The concentration of drug in blood samples will be measured by liquid chromatography equipped with mass spectroscopy detector. The study will be performed in Faculty of Pharmacy, Tabriz University of Medical Sciences. This study will be conducted without blinding.

Participants/Inclusion and exclusion criteria

Inclusion criteria: General Health (in terms of Liver, Heart and Kidney), Age (18-59 years old) Exclusion criteria: Smoking, History of cardiovascular, liver and kidney disease, Pregnancy, Alcohol and drug addiction, History of drug allergy.

Intervention groups

Intervention group will receive a single oral dose of test product (Sofosbuvir/Daclatasvir of Bakhtar Bioshimi Co.) and Control group will receive a single dose of reference product (Sofosbuvir/Daclatasvir of Gilead Co., Switzerland). Blood samples will be taken for 72 hours at the mentioned time points and the plasma will be stored in freezer until analysis. In both groups, breakfast and lunch will be served two and six hours after drug administration, respectively)

Main outcome variables

Drug plasma concentration

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20220211053992N8**
Registration date: **2023-05-13, 1402/02/23**
Registration timing: **prospective**

Last update: **2023-05-13, 1402/02/23**
Update count: **0**

Registration date

2023-05-13, 1402/02/23

Registrant information

Name

Hadi Valizadeh

Name of organization / entity

Country

Iran (Islamic Republic of)

Phone

+98 41 3334 8801

Email address

valizadehh@gmail.com

Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2023-06-10, 1402/03/20

Expected recruitment end date

2024-03-19, 1402/12/29

Actual recruitment start date

empty

Actual recruitment end date
empty
Trial completion date
empty

Scientific title
In vivo bioequivalence study of Sofosbuvir/Daclatasvir (400/60) manufactured by Bakhtar Bioshimi Co. compared with innovator product

Public title
Investigating the in vivo bioequivalence of Sofosbuvir/Daclatasvir tablet
Purpose
Other
Inclusion/Exclusion criteria
Inclusion criteria:
General Health (in terms of Liver, Heart and Kidney)
Exclusion criteria:
Smoking History of cardiovascular disease, liver and kidney disease Pregnancy Alcohol and drug addiction History of drug allergy
Age
From **18 years** old to **59 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
To randomly assign participants in two groups, 24 cards with numbers 1 to 24 will be used in closed envelopes that are arranged irregularly. Each candidate will pick up an envelope. Numbers 1-12 will be in group A and numbers 13-24 will be in group B. Group A will receive intervention 1 and group B will receive intervention 2, and after the first period, the interventions of both groups will change for the second period.
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 Tabriz University of Medical Sciences
Street address
No.2 Central Building 3rd Floor, Tabriz University of Medical Sciences, Daneshgah st.
City
Tabriz
Province
East Azarbaijan
Postal code
51664-14766
Approval date
2023-04-17, 1402/01/28
Ethics committee reference number
IR.TBZMED.REC.1402.090

Health conditions studied

1

Description of health condition studied
In the present study, the products will be administered to healthy volunteers.
ICD-10 code
ICD-10 code description

Primary outcomes

1

Description
Plasma concentration of drug
Timepoint
0.33-48 hours in predetermined time intervals after drug administration
Method of measurement
HPLC (High performance liquid chromatography)

Secondary outcomes

empty

Intervention groups

1

Description
Intervention group: Intervention group will receive a single oral dose of test product (Sofosbuvir400/Daclatasvir60 tablet manufactured by Bakhtar Bioshimi Co.) in fasted state. Blood samples will be collected for 72 hours at the mentioned times after drug administration and the concentration of drug in blood samples will be stored in freezer until analysis. Breakfast and lunch will be served two and six hours after drug administration, respectively.
Category
Treatment - Drugs

2

Description

Control group: Control group will receive a single oral dose of reference product (Sofosbuvir400/Daclatasvir60 tablet manufactured by Gilead Co. Switzerland) in fasted state. Blood samples will be collected for 72 hours at the mentioned times after drug administration and the concentration of drug in blood samples will be stored in freezer until analysis. Breakfast and lunch will be served two and six hours after drug administration, respectively.

Category

Treatment - Drugs

Recruitment centers

1

Recruitment center

Name of recruitment center

Faculty of Pharmacy, Tabriz University of Medical Sciences

Full name of responsible person

Hadi Valizadeh

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Faculty of Pharmacy, Tabriz University of Medical Sciences, Attar Neishaboori St., Golgash St.t

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Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Tabriz University of Medical Sciences

Full name of responsible person

Parviz Shahabi

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shahabip@tbzmed.ac.ir

Grant name

Grant code / Reference number

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

No

Title of funding source

Bakhtar Bioshimi 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

Industry

Person responsible for general inquiries

Contact

Name of organization / entity

Tabriz University of Medical Sciences

Full name of responsible person

Hadi Valizadeh

Position

Professor

Latest degree

Ph.D.

Other areas of specialty/work

Medical Pharmacy

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Faculty of Pharmacy, Tabriz University of Medical Sciences, Attar Neishabouri St., Golghasht St.

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Person responsible for scientific inquiries

Contact

Name of organization / entity

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Full name of responsible person

Hadi Valizadeh

Position

Professor

Latest degree

Ph.D.

Other areas of specialty/work

Medical Pharmacy

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Person responsible for updating data

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Position
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Sharing plan

Deidentified Individual Participant Data Set (IPD)
Undecided - It is not yet known if there will be a plan to make this available
Study Protocol
Undecided - It is not yet known if there will be a plan to make this available
Statistical Analysis Plan
Not applicable
Informed Consent Form
Undecided - It is not yet known if there will be a plan to make this available
Clinical Study Report
Undecided - It is not yet known if there will be a plan to make this available
Analytic Code
Not applicable
Data Dictionary
Undecided - It is not yet known if there will be a plan to make this available