Clinical Trial Protocol
Iranian Registry of Clinical Trials

10 Jun 2026

A randomized, open label, single dose, crossover, bioequivalence study of Fexofenadine 120mg tablet of Jaber Ebne Hayyan Pharm. Co., IRAN in comparison of Telfast 120mg tablet of Sanofi in 24 healthy adult subjects under fasting condition

Protocol summary

Study aim

A randomized, crossover bioequivalence study of single dose of test formulation (Fexofenadine 120mg tablet of Jaber Ebne Hayyan Pharm. Co.) in comparison of reference product (Telfast 120mg tablet) by means of AUC0-t (Area Under the Curve up to the last measurable concentration) and Cmax (maximum plasma concentration) in healthy adult human subjects under fasting conditions.

Design

A randomized, open label, single dose, crossover, bioequivalence study in 24 healthy subjects under fasting condition

Settings and conduct

This study is carried out in Core Research Center of Zahedan University of Medical Sciences located in Imam Ali Hospital in Zahedan. There is a separate space for sampling and forecasting emergency situations in order to accommodate and rest the volunteers. This crossover and open label study was performed on 24 healthy volunteers. The volunteers' health is verified by the project physician prior to entry into the study, and the volunteers' status is regularly monitored by the project physician on the day of drug administration. This study will be covered by insurance in order to compensate for any adverse effects.

Participants/Inclusion and exclusion criteria

Main Inclusion criteria: Healthy subjects aged between 18 -50 years old and weighted between 50 – 100 kg\\ Main exclusion criteria: Clinically relevant deviations from normal; Donation a unit of blood or participated in another clinical trial within the last two months; History of drug or alcohol abuse; Used any medication within 7-14 days before the first treatment;

Intervention groups

Intervention: Single dose of two Fexofenadine 120mg tablets of Jaber Ebne Hayyan Pharm. Co, IRAN Control: Single dose of two Telfast 120mg tablets of Sanofi

Main outcome variables

Plasma concentration of Hydrochlorothiazide at 0 (before dosing), 0.5, 1.0, 1.5, 2.0, 2.5, 3.0, 3.5, 4.0, 5.0, 6.0, 8.0, 10.0, 24.0 & 48.0 hr. after dosing

General information

Reason for update

Changing the drug dose from 180 mg tablet to 120 mg tablet

Acronym

IRCT registration information

IRCT registration number: **IRCT20190706044111N25**
Registration date: **2022-01-01, 1400/10/11**
Registration timing: **prospective**

Last update: **2023-08-20, 1402/05/29**
Update count: **1**

Registration date

2022-01-01, 1400/10/11

Registrant information

Name
Ladan Tayebi
Name of organization / entity
Pars Biopharmacy Research Co.
Country
Iran (Islamic Republic of)
Phone
+98 21 8895 6061
Email address
l.tayebi@parsbiopharmacy.com

Recruitment status

Recruitment complete

Funding source

Expected recruitment start date
2022-01-21, 1400/11/01
Expected recruitment end date
2022-09-22, 1401/06/31
Actual recruitment start date
empty
Actual recruitment end date
empty
Trial completion date
empty

Scientific title
A randomized, open label, single dose, crossover, bioequivalence study of Fexofenadine 120mg tablet of Jaber Ebne Hayyan Pharm. Co., IRAN in comparison of Telfast 120mg tablet of Sanofi in 24 healthy adult subjects under fasting condition

Public title
Bioequivalence study of Fexofenadine 120mg tablet of Jaber Ebne Hayyan Pharm. Co., IRAN
Purpose
Other
Inclusion/Exclusion criteria
Inclusion criteria:
- Aged between 18 - 50 years - Body weight between 50 – 100 kg - Having good health on the basis of medical history and physical & clinical examination - Understand the procedures and give written informed consent
Exclusion criteria:
Subject had undergone surgery of the gastro-intestinal tract treatment. Subject had donated a unit of blood or participated in another clinical trial, within the last two months before the first Subject had a history of drug or alcohol abuse. Subject who smokes more than 10 cigarettes per day. Subject had used any prescription medication within 14 days, or any non-prescription medication within 7 days, before the first treatment.
Age
From **18 years** old to **50 years** old
Gender
Both

Phase
Bioequivalence
Groups that have been masked
No information
Sample size
Target sample size: **48**
More than 1 sample in each individual
Number of samples in each individual: **2**
Each volunteer, 2 times take medicine in the study. One-time test product and the other time reference product with at least one week wash-out period
Randomization (investigator's opinion)
Randomized
Randomization description
Using the rand command in Excel software, one of the sequences AB (test-reference product) or BA (reference-test product) is randomly assigned to each volunteer at random.
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 Zahedan University of medical Sciences
Street address
Dr. Hessabi square Zahedan University of Medical Sciences
City
Zahedan
Province
Sistan-va-Balouchestan
Postal code
9816743463
Approval date
2021-12-12, 1400/09/21
Ethics committee reference number
IR.ZAUMS.REC.1400.313

Health conditions studied

1

Description of health condition studied
allergic rhinitis
ICD-10 code
Z88.9
ICD-10 code description
Allergy status to unspecified drug/meds/biol subst

Primary outcomes

1

Description
Plasma concentration of fexofenadine
Timepoint
at 0 (before dosing), 0.5, 1.0, 1.5, 2.0, 2.5, 3.0, 3.5, 4.0, 5.0, 6.0, 8.0, 10.0, 24.0 & 48.0 hr. after dosing
Method of measurement
High Performance Liquid Chromatography (HPLC)

Secondary outcomes

empty

Intervention groups

1

Description
Intervention group: two 120mg Fexofenadine tablets, produced by Jaber Ebne Hayyan Pharm. Co. (IRAN), single dose.
Category
Other

2

Description
Control group: Telfast, two 120mg tablets, produced by Sanofi company, single dose.
Category
Other

Recruitment centers

1

Recruitment center
Name of recruitment center
Core Research Lab. of ZAUMS
Full name of responsible person
Ghasemi Marzyeh
Street address
Emam Ali Hospital, Salamat Blv., Khalij-e-Fars Highway
City
Zahedan
Province
Sistan-va-Balouchestan
Postal code
9816743111
Phone
+98 54 3329 5664
Fax
+98 54 3329 5665
Email
crl@zaums.ac.ir
Web page address
http://crl.zaums.ac.ir/

Sponsors / Funding sources

1

Sponsor
Name of organization / entity
Jaber Ebne Hayyan Pharm. Co..
Full name of responsible person
Saffary Mostafa
Street address
Km 4 Karaj road
City
Tehran
Province
Tehran
Postal code
1398834511
Phone
+98 21 4450 3323
Fax
+98 21 4450 3530
Email
HeadOffice@jaber-pharma.com
Grant name
Grant code / Reference number
Is the source of funding the same sponsor organization/entity?
Yes
Title of funding source
Jaber Ebne Hayyan Pharm. Co..
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
Pars Biopharmacy Research Co.
Full name of responsible person
Ladan Tayebi
Position
Managing Director
Latest degree
Medical doctor
Other areas of specialty/work
Medical Pharmacy
Street address
1st floor, Saeidi Dd end, Felestin Ave.
City
Tehran
Province
Tehran
Postal code
1416673971
Phone
+98 21 8895 6061
Fax
+98 21 8896 9958
Email
l.tayebi@parsbiopharmacy.com

Person responsible for scientific inquiries

Contact
Name of organization / entity
Pars Biopharmacy Research Co.
Full name of responsible person
Ladan Tayebi

Position
Managing Director
Latest degree
Medical doctor
Other areas of specialty/work
Medical Pharmacy
Street address
1st floor, Saeidi Dd end, Felestin Ave.
City
Tehran
Province
Tehran
Postal code
1416673971
Phone
+98 21 8895 6061
Fax
+98 21 8896 9958
Email
l.tayebi@parsbiopharmacy.com

Person responsible for updating data

Contact
Name of organization / entity
Pars Biopharmacy Research Co.
Full name of responsible person
Ladan Tayebi
Position
Managing Director
Latest degree
Medical doctor
Other areas of specialty/work
Medical Pharmacy
Street address
1st floor, Saeidi Dd end, Felestin Ave.
City
Tehran
Province
Tehran
Postal code
1416673971
Phone
+98 21 8895 6061
Fax
+98 21 8896 9958
Email
l.tayebi@parsbiopharmacy.com

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
Undecided - It is not yet known if there will be a plan to make this available
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
Undecided - It is not yet known if there will be a plan to make this available
Data Dictionary
Undecided - It is not yet known if there will be a plan to make this available