Clinical Trial Protocol
Iranian Registry of Clinical Trials

16 Sep 2026

Comparative bioequivalence study of fexofenadin 30 mg/5 ml suspension of . and Allegra of SANOFI as reference in 24 healthy male under fasting.

Protocol summary

Study aim

Comparing the pharmacokinetics and invivo parameters of Karen Fexofenadine 30 mg/5 ml suspension with Allegra 5 mg Refrence Suspension to evaluate the equal effectiveness of these two formulations.

Design

Non-blinded, randomized, crossover in vivo bioequivalence study in 24 healthy males under fasting conditions. Block randomization for a treatment sequence of Test, Reference or Reference, Test is used.

Settings and conduct

During each study period, volunteers will receive a single dose intervention (1 or 2) in the Farabi Clinic (Eslamshahr, Tehran).18 blood samples were collected during 72 hours post intervention. A 7-day washout interval separated to study periods.

Participants/Inclusion and exclusion criteria

Healthy subjects (male) between 18 – 45 years of age and Body Mass Index (BMI) within 15% of normal range according to the accepted normal values between 18.5 and 30 (inclusive), calculated as kg/m2. Subjects with no significant diseases or clinically significant abnormal findings during screening, medical history, clinical examination and laboratory evaluations. Subjects with known allergy to fexofenadine or any inactive ingredients in the formulation. Any significant clinical disease or surgical procedure within 4 weeks prior to drug administration;

Intervention groups

Intervention group 1: Fexofenadine 30 mg/5 ml Suspension, produced by Darou Darman Pars. is the test product. In each period, 12 of 24 subjects will be given a single oral dose of this product. Intervention group 2: Allegra 30 mg/ 5 ml Suspension, produced by SANOFI is the reference product. In each period, 12 of 24 subjects will be given a single oral dose of this product.

Main outcome variables

Peak Plasma Concentration

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20180620040164N42**
Registration date: **2023-03-02, 1401/12/11**
Registration timing: **prospective**

Last update: **2023-03-02, 1401/12/11**
Update count: **0**

Registration date

2023-03-02, 1401/12/11

Registrant information

Name

Behzad Montaha Sangari

Name of organization / entity

Noor research and educational institute (Tavan)

Country

Iran (Islamic Republic of)

Phone

+98 21 6600 7026

Email address

info@tavaninstitute.ir

Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2023-04-25, 1402/02/05

Expected recruitment end date

2023-05-09, 1402/02/19

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title
Comparative bioequivalence study of fexofenadin 30 mg/5 ml suspension of . and Allegra of SANOFI as reference in 24 healthy male under fasting.

Public title
Comparative in vivo evaluation of 2 Fexofenadin 30 mg/5 ml Suspension formulations.

Purpose
Treatment

Inclusion/Exclusion criteria

Inclusion criteria:
Healthy subjects (male) between 18 – 45 years of age and Body Mass Index (BMI) within 15% of normal range according to the accepted normal values between 18.5 and 30 (inclusive), calculated as kg/m2. Subjects with no significant diseases or clinically significant abnormal findings during screening, medical history, clinical examination and laboratory evaluations. Subjects with normal vital signs. Subjects who agree with patient consent form.

Exclusion criteria:
• Subjects with known allergy to fexofenadine or any inactive ingredients in the formulation. • Any significant clinical disease or surgical procedure within 4 weeks prior to drug administration; • Any significant clinical abnormality detected during screening; • Abnormal vital signs during screening (Systolic blood pressure less than 90 or more than 140 mm Hg or diastolic blood pressure less than 50 mm Hg or more than 90 mm Hg or Pulse rate less than 50/minute or more than 100/minute). • Smoking more than 10 cigarettes per day and could not tolerate cigarette cessation during each clinical period; • Subjects who has used any drug including Over-The-Counter (OTC) drugs within 7 days prior to the start of the study or prescription drugs (within 14 days) and might need drug intake during study period; • History of alcohol or drug abuse within 2 years before the start of the study; • Heavy drinker of caffeine, grapefruit juice or caffeinated drinks or who are on special diet (such as vegetarians) or do exertional physical activity; • A history of difficulty with donating blood or donation of more than 500 ml blood within 7 days prior to the start of the study.

Age
From **18 years** old to **45 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
The randomization schedule will be generated with https://www.sealedenvelope.com/simple-randomiser/v1/lists. A 2*2 block randomization list is created. We have 12 blocks and within each two volunteer numbers (allocated after screening) for all 24 volunteers. According to this list, a treatment sequence of Test, Reference or Reference, Test will be given to each volunteer.

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, School of Pharmacy, Nursing&Midwifery Shahid Beheshti University of medical scienc

Street address
Niayesh Highway, Valiasr Ave, Tehran, Iran

City
Tehran

Province
Tehran

Postal code
1996835113

Approval date
2022-08-09, 1401/05/18

Ethics committee reference number
IR.SBMU.PHARMACY.REC.1401.083

Health conditions studied

1

Description of health condition studied
Allergic rhinitis, unspecified

ICD-10 code
J30.9

ICD-10 code description
Allergic rhinitis, unspecified

Primary outcomes

1

Description
Peak Plasma Concentration (Cmax)

Timepoint
14 blood samples will be withdrawn pre-dose and at 20, 40, 60, 90 and 2, 2/5, 3, 4, 6, 8, 11, 24, 48 hours after intervention.

Method of measurement
Using non-compartmental model of Win-Nonlin Professional software version 3.2.A (Pharsight

Corporation, USA)

Secondary outcomes

1

Description
AUC (Area Under the Concentration-Time Curve)
Timepoint
14 blood samples will be withdrawn pre-dose and at 20, 40, 60, 90 and 2, 2/5, 3, 4, 6, 8, 11, 24, 48 hours after intervention.
Method of measurement
Using non-compartmental model of Win-Nonlin Professional software version 3.2.A (Pharsight Corporation, USA)

Intervention groups

1

Description
Intervention group 1: Fexofenadine 30 mg/ 5 ml Suspension , produced by Darou darman Pars. is the test product. In each period, 12 of 24 subjects will be given single oral dose of this product. After 7-day wash-out period the intervention 2 will be given to these subjects.
Category
Treatment - Drugs

2

Description
Intervention group 2: Allegra 30 mg/ 5 ml Suspension, produced by SANOFI is the reference product. In each period, 12 of 24 subjects will be given single oral dose of this product. After 7-day wash-out period the intervention 1 will be given to these subjects.
Category
Treatment - Drugs

Recruitment centers

1

Recruitment center
Name of recruitment center
Hakim Farabi Clinic
Full name of responsible person
Ebrahim Siahpoosh
Street address
No. 57, Shemshad alley, in front of Sallor town
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4635314588
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Sponsors / Funding sources

1

Sponsor
Name of organization / entity
Darou darman Pars Co.
Full name of responsible person
Mohsen Hashemi
Street address
No 27, corner of Orkideh Alley, West Emdad St. North Sheikh Bahaei St. Tehran
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Tehran
Postal code
1459926609
Phone
+98 21 8861 0479
Email
info@ddp-group.com
Grant name
Grant code / Reference number
Is the source of funding the same sponsor organization/entity?
Yes
Title of funding source
Darou darman Pars 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
Noor Research & Development Institute
Full name of responsible person
Ali Aghaei
Position
Master
Latest degree
Master
Other areas of specialty/work
Pharmacy
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Province
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Email
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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
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
No - There is not a plan to make this available