

Clinical Trial Protocol

Iranian Registry of Clinical Trials

09 Jun 2026

Comparative bioequivalence study of Loratadine 10 mg Tablet of Karen Pharma and Food Supplement Co. and Claritine® of NBAYER as reference in 24 healthy male under fasting.

Protocol summary

Study aim

This study will be performed to compare the pharmacokinetics and in vivo parameters of Loratadine 10 mg Tablet formulation as a test product with Claritine 10 mg Tablet formulation as a reference product to evaluate the bioequivalence.

Design

Non blinded, randomized, crossover in vivo bioequivalence study in 24 healthy male under fasting condition. Block randomization for a treatment sequence of Test/Reference or Reference/Test will be used.

Settings and conduct

In each period, volunteers will receive a single dose intervention (1 or 2) in the Farabi Clinic (Eslamshahr, Tehran) according to a prepared block randomization schedule without blinding. 16 blood samples were collected during 72 hours post intervention. A 14-day washout interval separated 2 study periods.

Participants/Inclusion and exclusion criteria

Healthy subjects (male) between 20 - 45 years of age and Body Mass Index (BMI) within 15% of the 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; laboratory evaluations; known allergy to loratadine; history of hypertension.

Intervention groups

Intervention group 1: Loratadine 10 mg Tablet, produced by Karen is the test product. In each period, 12 of 24 subjects will be given a single oral dose of this product. After 7-day wash-out period the intervention 2 will be given to these subjects. Intervention group 2: Claritine 10 mg Tablet, produced by Novartis is the reference product. In each period, 12 of 24 subjects will be given a single oral dose of this product. After 7-day wash-out period the intervention 1 will be given to these subjects.

Main outcome variables

Peak Plasma Concentration

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20180620040164N41**

Registration date: **2023-02-25, 1401/12/06**

Registration timing: **prospective**

Last update: **2023-02-25, 1401/12/06**

Update count: **0**

Registration date

2023-02-25, 1401/12/06

Registrant information

Name

Behzad Montaha Sangari

Name of organization / entity

Noor research and educational institute (Tavan)

Country

Iran (Islamic Republic of)

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+98 21 6600 7026

Email address

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Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2023-04-26, 1402/02/06

Expected recruitment end date

2023-05-10, 1402/02/20

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Comparative bioequivalence study of Loratadine 10 mg Tablet of Karen Pharma and Food Supplement Co. and Claritine® of NBAYER as reference in 24 healthy male under fasting.

Public title

Comparative in vivo evaluation of 2 Loratadine 10 mg Tablet formulations.

Purpose

Treatment

Inclusion/Exclusion criteria**Inclusion criteria:**

Healthy subjects (male) between 20 – 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 loratadine. Had history of hypertension. Had Concurrently used enzyme modifying drugs especially erythromycin, MAO inhibitors, ketoconazole, and cimetidine. Had recent history of abdominal pain, epistaxis or sleep disturbances. Had history of any psychiatric illness, which may impair the ability to provide, written informed consent. Smoking more than 10 cigarettes per day and could not tolerate cigarette cessation during each clinical period. Consumption of enzyme modifying drugs within 30 days prior to Day 1 of this study. History of alcohol or drug abuse. 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 **20 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's number (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 of School of Pharmacy and Nursing & Midwifery- Shahid Beheshti University of Medica

Street address

Niayesh Highway, Valiasr Ave, Tehran, Iran

City

Tehran

Province

Tehran

Postal code

1996835113

Approval date

2023-01-24, 1401/11/04

Ethics committee reference number

IR.SBMU.PHARMACY.REC.1401.235

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 (C_{max})

Timepoint

Before intervention and then at 0.25, 0.5, 0.75, 1, 1.25, 1.5, 2, 2.5, 3, 4, 6, 8, 10, 12, 24, 48 and 72 hours post intervention in each period

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

Before intervention and then at 0.25, 0.5, 0.75, 1, 1.25, 1.5, 2, 2.5, 3, 4, 6, 8, 10, 12, 24, 48 & 72 hours post intervention in each period

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: Loratadine 10 mg tablet, produced by Karen 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: Loratadine 10 mg tablet produced by BAYER 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, Sallor city

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4635314588

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Email

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Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Karen Pharma and Food Supplement Co.

Full name of responsible person

Zahra Mortazavi

Street address

No: 3, Western Nahid st. Africa Blvd.

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Province

Tehran

Postal code

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Phone

+98 21 2620 4283

Email

info@karenpharma.com

Grant name

Grant code / Reference number

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

Yes

Title of funding source

Karen Pharma and Food Supplement 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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Person responsible for scientific inquiries

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Person responsible for updating data

Contact

Name of organization / entity
Tavan Institute
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Latest degree
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Other areas of specialty/work
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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

It's not specified yet.

Study Protocol

Undecided - It is not yet known if there will be 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