Clinical Trial Protocol
Iranian Registry of Clinical Trials

01 Jul 2026

Comparative bioequivalence study of the Desloratadine 5-mg Tablets manufactured by Behestan Pharmaceutical Company with Desloratadine brand tablets (Clarinex®) by Organon company

Protocol summary

Study aim

Demonstration of bioequivalence of the Desloratadine 5-mg tablets of Behestan Pharmaceutical Company with Clarinex® tablet manufactured by Organon after single dose administration.

Design

Single dose, randomized and crossover bioequivalence study of Desloratadine 5-mg tablets of Behestan Pharmaceutical Company with Clarinex® (Organon Co.) in 24 healthy male volunteers in two groups

Settings and conduct

Study place and the place for blood sample analysis are the Drug Applied Research Center affiliated to Tabriz University of Medical Science, respectively. 24 healthy male volunteers will receive Desloratadine 5 mg tablets test or reference in random sequence according to the randomization schedule. The interval between receiving the medicine (washout period) is 7 days, If the first sequence receives Iranian medicine, they will receive brand medicine. Blood samples will be taken from all participants before and after receiving the drug at 1, 2, 2.5, 3, 3.5, 4, 5, 6, 8, 10, 12, 24, 48 and 72 hours after dosing.

Participants/Inclusion and exclusion criteria

Inclusion criteria: Healthy male subjects in the age range of 18-60 years and BMI (Body Mass Index) of 18-30. Exclusion criteria: Subjects with Blood Pressure ≤ 90/60 mm/Hg or BP ≥ 140/90 mm/Hg. Any evidence of impairment of renal, hepatic, cardiac, lung or gastrointestinal function or a history of tuberculosis, epilepsy, asthma, diabetes, psychosis or glaucoma and regular smoker.

Intervention groups

Intervention group 1: Desloratadine 5-mg tablets of Behestan Pharmaceutical Company is the test product. Intervention group 2: Clarinex® by Organon company is the reference product. In each period, 12 of 24 subjects will be given single dose of this product. After the washout period, the volunteers are placed in the opposite group.

Main outcome variables

Peak Plasma Concentration (Cmax); Area under the concentration-time curve (AUC)

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20200407046981N50**
Registration date: **2022-11-12, 1401/08/21**
Registration timing: **prospective**

Last update: **2022-11-12, 1401/08/21**
Update count: **0**

Registration date

2022-11-12, 1401/08/21

Registrant information

Name

Fatima Molavi

Name of organization / entity

Country

Iran (Islamic Republic of)

Phone

+98 41 3336 2700

Email address

molavif@tbzmed.ac.ir

Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2022-12-18, 1401/09/27

Expected recruitment end date

2023-02-16, 1401/11/27

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Comparative bioequivalence study of the Desloratadine 5-mg Tablets manufactured by Behestan Pharmaceutical Company with Desloratadine brand tablets (Clarinex®) by Organon company

Public title

Study of absorption and elimination rate of Desloratadine 5-mg tablets in comparison with Desloratadine brand tablets (Clarinex®).

Purpose

Treatment

Inclusion/Exclusion criteria

Inclusion criteria:

The weight limit of each volunteer should be between 60 and 100 kg. All volunteers must be non-smokers. They must be healthy in terms of liver, kidney, respiratory system, mental and other general health characteristics that will be assessed. Candidates who have consented to the consent form

Exclusion criteria:

Known hypersensitivity or idiosyncratic reaction to Desloratadine or any ingredients. Subjects with BP ≤ 90/60 mm/Hg or BP ≥ 140/90 mm/Hg. Taking any medicine during two week before dosing.

Age

From **18 years** old to **60 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 people 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 after entering the study, and 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 the 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 Science

Street address

Third floor, central building No. 2, Golgasht street, Tabriz University of Medical Science, Tabriz, Iran

City

Tabriz

Province

East Azarbaijan

Postal code

5166614766

Approval date

2022-10-31, 1401/08/09

Ethics committee reference number

IR.TBZMED.REC.1401.685

Health conditions studied

1

Description of health condition studied

Bioequivalence study

ICD-10 code

ICD-10 code description

Primary outcomes

1

Description

Peak Plasma Concentration (Cmax)

Timepoint

0 (before dosing), 1, 2, 2.5, 3, 3.5, 4, 4.5, 5, 6, 8, 10, 12, 24, 48 and 72 hour after dosing

Method of measurement

High-performance liquid chromatography—mass spectrometry (HPLC-MS)

Secondary outcomes

1

Description

AUC (Area Under the Concentration-Time Curve

Timepoint

0 (before dosing), 1, 2, 2.5, 3, 3.5, 4, 4.5, 5, 6, 8, 10, 12, 24, 48 and 72 hour after dosing

Method of measurement

Using non-compartmental model of Win-Nonlin

Professional software version 3.2.A (Pharsight Corporation, USA) or SPSS

Intervention groups

1

Description
Intervention group1: In this group, volunteers are given a single oral dose of Desloratadine 5-mg Tablets manufactured by Behestan Pharmaceutical Co. (Domestic). In each period, 12 of 24 subjects will be given single oral dose of this product. After the washout period, the volunteers are placed in the Intervention group 2

Category
Treatment - Drugs

2

Description
Intervention group: In this group, volunteers are given a single oral dose of Desloratadine 5-mg (Clarinex®), produced by Organon Company (Brand). In each period, 12 of 24 subjects will be given single oral dose of this product. After the washout period, the volunteers are placed in the Intervention group 1

Category
Treatment - Drugs

Recruitment centers

1

Recruitment center

Name of recruitment center
Drug Applied Research Center

Full name of responsible person
Dr Hamed Hamishehkar

Street address
Drug Applied Research Center, In front of Shahid Madani Hospital, Daneshghah Blvd, Tabriz, Iran

City
Tabriz

Province
East Azarbaijan

Postal code
5165665811

Phone
+98 41 3336 7914

Fax
+98 41 3336 7914

Email
hamishehkar.hamed@gmail.com

Web page address
https://darc.tbzmed.ac.ir/

Sponsors / Funding sources

1

Sponsor

Name of organization / entity
Behestan Pharmaceutical Company

Full name of responsible person
Mahdi Orouji

Street address
Behestan bldg., #10 Pardis st., Mollasadra Ave. Tehran 1991915613, Iran

City
Tehran

Province
Tehran

Postal code
141554318

Phone
+98 21 8877 4200

Email
info@behestandarou.com

Grant name

Grant code / Reference number

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

Title of funding source
Behestan 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
Fatima Molavi

Position
Non-Faculty Academic Position

Latest degree
Ph.D.

Other areas of specialty/work
Pharmaceutics

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East Azarbaijan

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Phone
+98 41 3336 2700

Fax

Email
Molavif@tbzmed.ac.ir

Person responsible for scientific inquiries

Contact

Name of organization / entity
Tabriz University of Medical Sciences

Full name of responsible person
Hamed Hamishehkar

Position
Professor

Latest degree
Ph.D.

Other areas of specialty/work
Pharmaceutics

Street address
Drug Applied Research Center, In front of Shahid Madani Hospital, Daneshghah Blvd, Tabriz, Iran

City
Tabriz

Province
East Azarbaijan

Postal code
5165665811

Phone
+98 41 3336 7914

Email
Hamishehkar.hamed@gmail.com

Person responsible for updating data

Contact

Name of organization / entity
Tabriz University of Medical Sciences

Full name of responsible person
Fatima Molavi

Position
Non-Faculty Academic Position

Latest degree
Ph.D.

Other areas of specialty/work
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Province
East Azarbaijan

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5166614766

Phone
+98 41 3336 2700

Fax

Email
Molavif@tbzmed.ac.ir

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
There is no further information

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

Analytic Code
Not applicable

Data Dictionary
Not applicable