Clinical Trial Protocol
Iranian Registry of Clinical Trials

17 Sep 2026

Bioequivalence Study of desloratadine 5 mg manufactured by Pharma Chemi and Clarinex manufactured by Schering in 24 Healthy Volunteers under fasting condition

Protocol summary

Study aim
Bioequivalence of desloratadine tablets of Pharmachemi company with Clarinex tablets of Schering company (Germany)

Design
Cross over bioequivalence study

Settings and conduct
Sampling of volunteers is done in Khorazmi Plasma Center in Islamshahr. On the day of sampling, two 5 mg tablets of manufactured by Pharmachemi or Schering on two occasions and with a washout period of 7 days, will be administered orally with 240 ml of water to the volunteer. For example, if in the first phase he received the medicine made by Pharmachemi company, he will receive the brand medicine one week later. In each phase, 5 cc of blood sample will be taken before drug administration and at times 0.5, 1, 1.5, 2, 2.5, 3, 3.5, 4, 4.5, 5, 6, 8, 10 , 24 ,48, 72 hours after prescribing the medicine . One week after the start of the study, the volunteer's cooperation in this research ends. The way to cooperate in these three weeks is that the drug is prescribed in the first day and after that 72 hours blood sampling is done at the mentioned times after washout period of one week the other drug is administered and blood samples will be taken at the same time

Participants/Inclusion and exclusion criteria
inclusion criteria: A healthy male or female volunteer between the ages of 18 and 55 with a body mass index (BMI) between 19 and 30 - People who are willing to sign an informed consent form. Exclusion criteria:

Intervention groups
12 people who take Pharmachemi tablets The second group: 12 people who take Schering pills on the same day

Main outcome variables
Plasma concentration and area under the curve of plasma concentration time of test and reference drug

General information

Reason for update

Acronym

IRCT registration information
IRCT registration number: **IRCT20220209053979N7**
Registration date: **2023-04-29, 1402/02/09**
Registration timing: **retrospective**

Last update: **2023-04-29, 1402/02/09**
Update count: **0**

Registration date
2023-04-29, 1402/02/09

Registrant information

Name
Roya Talari

Name of organization / entity

Country
Iran (Islamic Republic of)

Phone
+98 21 8880 0892

Email address
talari_r@yahoo.com

Recruitment status
Recruitment complete

Funding source

Expected recruitment start date
2023-04-21, 1402/02/01

Expected recruitment end date
2023-04-28, 1402/02/08

Actual recruitment start date
empty

Actual recruitment end date
empty

Trial completion date
empty

Scientific title
Bioequivalence Study of desloratadine 5 mg manufactured by Pharma Chemi and Clarinex manufactured by Schering in 24 Healthy Volunteers under fasting condition

Public title
Bioequivalence Study of desloratadine 5 mg manufactured by Pharma Chemi and Clarinex manufactured by Schering

Purpose
Other

Inclusion/Exclusion criteria
Inclusion criteria:
Healthy male or female volunteers between the age of 18 and 55 with a body mass index (BMI) between 19 and 30 volunteers who are willing to sign an informed consent form
Exclusion criteria:
History of allergy to desloratadine or formulation components History or significant clinical evidence of any disease Taking any type of medicine in the 14 days before the start of the study Participation in any clinical study within 30 days prior to study initiation

Age
From **18 years** old to **55 years** old

Gender
Both

Phase
Bioequivalence

Groups that have been masked

- Participant
- Data analyser

Sample size
Target sample size: **24**
More than 1 sample in each individual
Number of samples in each individual: **16**
5 mililitr blood sample is taken from each volunteer

Randomization (investigator's opinion)
Randomized

Randomization description
Using the rand option of the Excel software, the candidates are divided into two groups, and half of them will receive numbers 1-12 and the test drug, and the other half will receive numbers 13-24 and will receive the reference drug.

Blinding (investigator's opinion)
Double blinded

Blinding description
The tablets of Pharmachemi and Schering are both circular and white , so the candidate does not know which company's drug he will receive in each phase of the study. Additionally, the tubes of the volunteers' samples are also coded, so the analyzer does not know which company's drug he is analyzing, so only the researcher and the prescriber know which company's drug is being prescribed.

Placebo
Not used

Assignment
Crossover

Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee
Name of ethics committee
Ethics Committee of Tehran University of Medical Science
Street address
Tehran University of Medical Science, 16 Azar St.,
City
Tehran
Province
Tehran
Postal code
1417713135

Approval date
2023-04-07, 1402/01/18

Ethics committee reference number
IR. TUMS. TIPS. REC. 1402. 001

Health conditions studied

1

Description of health condition studied
A crossover bioequivalence study in 24 healthy volunteers

ICD-10 code

ICD-10 code description

Primary outcomes

1

Description
Plasma concentration time profile, maximum plasma concentration, AUC

Timepoint
0, 0,5, 1, 1.5, 2, 2.5, 3, 3.5, 4, 5, 6, 8, 10, 24, 48, 72 hours after drug administration

Method of measurement
Liquid chromatography with mass spectrophotometry

Secondary outcomes

empty

Intervention groups

1

Description
Intervention group: 1: Oral administration of two tablets of desloratadine 5 mg manufactured by Pharmachemi/ Schering Company to 12 healthy volunteers under

fasting condition with 240 ml of water. Then 16 blood samples are taken from each volunteers at certain time.

Category

Treatment - Drugs

2

Description

Intervention group 2: Oral administration of two tablets of desloratadine 5 mg manufactured by Schering/ Pharmachemi Company to 12 healthy volunteers under fasting condition with 240 ml of water. Then 16 blood samples are taken from each volunteers at certain time.

Category

Treatment - Drugs

Recruitment centers

1

Recruitment center

Name of recruitment center

Kharazmi plasma center

Full name of responsible person

Sara Solgi

Street address

No. 13, Shehamat 1st Alley, Ali Ibn Abitalib St., Namaz Square,

City

Islamshahr

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Tehran

Postal code

3313679886

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+98 21 5669 4726

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+98 21 5637 8236

Email

Info@kpcir.com

Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Pharmachemi Company

Full name of responsible person

Dr.Hosseini

Street address

Azadegan highway, 7 km of Karaj special road

City

Tehran

Province

Tehran

Postal code

111551576

Phone

+98 21 4452 5190

Fax

+98 21 4450 3796

Email

support@rpsi.ir

Grant name

Grant code / Reference number

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

Yes

Title of funding source

Pharmachemi 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

Kharazmi Plasma Center

Full name of responsible person

Roya Talari

Position

excutor

Latest degree

Ph.D.

Other areas of specialty/work

Medical Pharmacy

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Person responsible for updating data

Contact
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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
The bioequivalence study data is completely confidential and according to the contract with Pharmachemi Company, it should not be published anywhere.
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