Clinical Trial Protocol
Iranian Registry of Clinical Trials

05 Jul 2026

Comparative bioequivalence study of the Cefixime 400-mg Tablets manufactured by Yasin Shafa Hamoun Company

Protocol summary

Study aim

Examining the bioequivalency of domestically produced the Cefixime 400-mg tablets manufactured by Yasin Shafa Hamoun Company with brand samples(CEFIXORAL®)

Design

A single dose, not blinded, randomized, bioequivalence clinical trial on 24 healthy volunteers.

Settings and conduct

The number of 24 healthy in the age range of 18-60 years and the Body Mass Index range of 18-30, who are voluntarily selected through public notification. One tablet is taken fasting and blood is taken at 15 times point. One week later, the process is repeated for the brand medicine

Participants/Inclusion and exclusion criteria

The weight range of participating candidates should be between 60-100 kg; All candidates must be non-smokers; Candidates should be healthy in terms of physical examination, ECG and the following laboratory tests: Hemoglobin, Hematocrit, Red and White Blood Count, MCV (Mean Body Volume), MCH (Mean Body Hemoglobin), Routine Urinalysis, Total Cholesterol, Triglyceride, Total Proteins, albumin, uric acid, total bilirubin, alkaline phosphatase, gamma glutamyl transpeptidase (γ-GT), aspartate aminotransferase (AST), alanine aminotransferase (ALT), urea, creatinine and fasting blood glucose Volunteers who have agreed to an informed consent form.

Intervention groups

After taking a Cefixime 400-mg tablets from domestic company, 3 milliliters of blood will be collected from the volunteer in 15 times intervals for 24 hours. one week later, the process is repeated for a brand sample tablet. The drug concentration is measured in plasma

Main outcome variables

Studying the Drug pharmacokinetic parameters including measuring the plasma concentrations of drugs for brand and test products, determining the desired and important pharmacokinetic parameters in bioequivalence studies, AUCs, Tmax, Cmax, T1/2

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20130313012810N20**
Registration date: **2023-12-24, 1402/10/03**
Registration timing: **prospective**

Last update: **2023-12-24, 1402/10/03**
Update count: **0**

Registration date

2023-12-24, 1402/10/03

Registrant information

Name

Hamed Hamishehkar

Name of organization / entity

Drug Applied Research Center, Tabriz University of Medical Sciences

Country

Iran (Islamic Republic of)

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Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2023-12-30, 1402/10/09

Expected recruitment end date

2024-01-05, 1402/10/15

Actual recruitment start date

empty

Actual recruitment end date
empty
Trial completion date
empty

Scientific title
Comparative bioequivalence study of the Cefixime 400-mg Tablets manufactured by Yasin Shafa Hamoun Company

Public title
Comparative bioequivalence study of the Cefixime 400-mg Tablets manufactured by Yasin Shafa Hamoun Company
Purpose
Other
Inclusion/Exclusion criteria
Inclusion criteria:
The weight range of participating candidates should be between 60-100 kg Candidates should be healthy in terms of physical examination, ECG and the following laboratory tests: Hemoglobin, Hematocrit, Red and White Blood Count, MCV (Mean Body Volume), MCH (Mean Body Hemoglobin), Routine Urinalysis, Total Cholesterol, Triglyceride, Total Proteins, albumin, uric acid, total bilirubin, alkaline phosphatase, gamma glutamyl transpeptidase (γ-GT), aspartate aminotransferase (AST), alanine aminotransferase (ALT), urea, creatinine and fasting blood glucose Volunteers who have agreed to an informed consent form All candidates should not consume caffeine-containing drinks and chocolate during two days before the prescription, and this restriction must be followed until the last blood draw
Exclusion criteria:
History of allergic or adverse reaction to Cefixime or any similar product Volunteers with blood pressure less than 60/90 mm Hg or higher than 90/140 mm Hg Smokers Individuals who donated whole blood or blood components within 2 months within 2 weeks prior to the first dose of the study product(s)
Age
From **18 years** old to **60 years** old
Gender
Both

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 Sciences
Street address
Daneshghah St. Drug Applied Research Center
City
Tabriz
Province
East Azarbaijan
Postal code
5165665811
Approval date
2023-12-17, 1402/09/26
Ethics committee reference number
IR.TBZMED.REC.1402.700

Health conditions studied

1

Description of health condition studied
Bioequivalence study in healthy volunteers
ICD-10 code
ICD-10 code description

Primary outcomes

1

Description
Plasma concentration of the drug
Timepoint
15 sampling time included pre-dose (time 0) and at the following hours post-dose: 0.5, 1, 1.5, 2, 2.5, 3, 3.5, 4, 5, 6, 8, 10, 12, and 24 h
Method of measurement
Liquid Chromatography with tandem mass spectrometry (LC-MS-MS)

Secondary outcomes

empty

Intervention groups

1

Description
Intervention group: This study examines the bioequivalence of the Cefixime tablet produced by a domestic company with a foreign brand sample. We have only one intervention group and there is no control group. The intervention group, which includes healthy, fasting volunteers, will receive a single dose, 400 mg tablet manufactured by the pharmaceutical company Yasin Shafa Hamoun and CEFIXORAL® brand, in two 24-hour periods with an interval of one week, on the day of the study. And in 15 different time periods up to 24 hours after taking the medicine, blood samples will be taken from the volunteers in the amount of 3 ml each time, that is, a total of 45 ml within 24 hours. The training that will be given to the volunteers includes avoiding the consumption of drinks containing alcohol and xanthine and other interfering drugs in the prescription drug from 48 hours before the start of the study until the end of the study.

Category
Other

Recruitment centers

1

Recruitment center

Name of recruitment center
Drug Applied Research Center, Tabriz University of Medical Sciences

Full name of responsible person
Hamed Hamishehkar

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Sponsors / Funding sources

1

Sponsor

Name of organization / entity
شرکت یاسین شفا هامون

Full name of responsible person
Masumeh Abiri

Street address
ground floor, No. 0, Ishraq Boulevard, Imam Khomeini Boulevard, Imam Hassan Mosque neighborhood, Qom

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3719817417

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Email
info@hamonpharma.com

Grant name

Grant code / Reference number

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

Title of funding source
شرکت یاسین شفا هامون

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
Hamed Hamishehkar

Position
Professor

Latest degree
Ph.D.

Other areas of specialty/work
Medical Pharmacy

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Person responsible for scientific inquiries

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Position
Professor

Latest degree
Ph.D.

Other areas of specialty/work
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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