

# 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 ( $\gamma$ -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, T<sub>max</sub>, C<sub>max</sub>, T<sub>1/2</sub>

#### 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)

##### Phone

+98 41 1336 3311

##### Email address

hamishehkar.hamed@gmail.com

##### 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 ( $\gamma$ -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**

Daneshgah 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

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### 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

#### Street address

Drug Applied Research Center, Tabriz University of Medical Sciences

#### City

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#### Province

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#### Postal code

51656-65811

#### Phone

+98 41 3336 3311

#### Email

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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

### City

Qom

### Province

Ghoum

### Postal code

3719817417

### Phone

+98 21 4496 8231

### 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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#### Web page address

<http://darc.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

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Ph.D.

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## Person responsible for updating data

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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