Clinical Trial Protocol
Iranian Registry of Clinical Trials

09 Nov 2026

Comparative bioequivalence study of Itraconazole 100-mg capsules manufactured by Kimiara Heram Pharmaceutical Company versus Sporanox® (Janssen-Cilag Ltd)

Protocol summary

Study aim

Demonstration of bioequivalence of Itraconazole 100-mg Capsule of Kimiara Heram Pharmaceutical Company with Sporanox® capsule manufactured by Janssen-Cilag Ltd after single dose administration.

Design

Single dose, randomized and crossover bioequivalence study of Itraconazole 100-mg Capsule by Kimiara Heram Co. with Sporanox® (Janssen-Cilag Ltd) in 24 healthy male volunteers in two groups under fasting condition.

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 each of test or reference Itraconazole 100-mg capsule in random sequence according to the randomization schedule. The interval between receiving the medicine (washout period) is 14 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, 1.5, 2, 2.5, 3, 3.5, 4, 5, 6, 10, 12, 24, 36, 48, 72 and 96 hours after dosing.

Participants/Inclusion and exclusion criteria

Inclusion criteria: Healthy male subjects in the age range of 18-55 years and BMI (Body Mass Index) of 18.5-30. Exclusion criteria: Subjects with BP ≤ 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 TB, epilepsy, asthma, DM, psychosis or glaucoma and regular smoker.

Intervention groups

Intervention group 1: Itraconazole 100-mg capsule by Kimiara Heram Co. is the test product. Intervention group 2: Sporanox® (Janssen-Cilag Ltd) 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: **IRCT20200407046981N25**
Registration date: **2022-02-21, 1400/12/02**
Registration timing: **prospective**

Last update: **2022-02-21, 1400/12/02**
Update count: **0**

Registration date

2022-02-21, 1400/12/02

Registrant information

Name

Fatima Molavi

Name of organization / entity

Country

Iran (Islamic Republic of)

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Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2022-09-22, 1401/06/31

Expected recruitment end date

2022-12-21, 1401/09/30

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Comparative bioequivalence study of Itraconazole 100-mg capsules manufactured by Kimiara Heram Pharmaceutical Company versus Sporanox® (Janssen-Cilag Ltd)

Public title

Study of absorption and elimination rate of Itraconazole 100-mg capsule in comparison with Itraconazole brand Capsule (Sporanox®).

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 Itraconazole or any ingredients. Subjects with BP ≤ 90/60 mm/Hg or BP ≥ 140/90 mm/Hg. Regular smoker who smokes more than ten cigarettes daily. Taking any medicine during two weeks 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**

More than 1 sample in each individual

Number of samples in each individual: **2**

Candidates of the sequences must take one of the domestic or brand drugs, if the first sequence of the volunteers received the domestic drug after the washout period, they must receive the brand drug. In fact, every single volunteers is used as control for himself.

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

2022-02-01, 1400/11/12

Ethics committee reference number

IR.TBZMED.REC.1400.1122

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

At 0 before dosing 1, 1.5, 2, 2.5, 3, 3.5, 4, 5, 6, 10, 12, 24, 36, 48, 72 and 96 hours 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

At 0 before dosing 1, 1.5, 2, 2.5, 3, 3.5, 4, 5, 6, 10, 12, 24, 36, 48, 72 and 96 hours 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 group 1: In this group, volunteers are given a single oral dose of Itraconazole 100-mg capsule produced by Kimiara Heram 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 2: In this group, volunteers are given a single oral dose of Itraconazole 100-mg Capsule (Sporanox), produced by Janssen-Cilag Ltd 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

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Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Kimiara Heram Company

Full name of responsible person

Omid Rahbar Safa

Street address

Iran, Tehran, Gandi St. North, Sharifi St., No. 27

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Province

Tehran

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Email

khatami@kimiara.com

Grant name

Grant code / Reference number

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

Yes

Title of funding source

Kimiara Heram 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

Hamed Hamishehkar

Position

Professor

Latest degree

Ph.D.

Other areas of specialty/work

Pharmaeutics

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Person responsible for scientific inquiries

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Fatima Molavi
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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
No - There is not a plan to make this available
Study Protocol
Undecided - It is not yet known if there will be a plan to make this available
Statistical Analysis Plan
Undecided - It is not yet known if there will be 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
No - There is not a plan to make this available
Data Dictionary
Undecided - It is not yet known if there will be a plan to make this available