

Clinical Trial Protocol

Iranian Registry of Clinical Trials

03 Jun 2026

Pharmacokinetic assessments of Itraconazole capsules in comparison with brand drug SPRANOX

Protocol summary

Study aim

In- Vivo Bioequivalence study of Itraconazole Capsules 100mg Kimidarou in comparison with brand drugs SPRANOX® 100mg Cps, Janssen-Cilag Pharma. Belgium.

Design

Single dose Itraconazole Capsules 100mg Kimidarou

Settings and conduct

This study will be conducted in two-way, cross-over and fasting, and on two sets of healthy volunteers. The study will be conducted in two periods of twenty-four hours. The interval between these two periods, which is called the wash-out time, is determined by the half-life of the drug plasma, which according to scientific sources should be at least 5 to 7 half-life of the drug in the case of the drug under study. The plan will take a week to clean up the drug, given the biological half-life of the drugs in the drug form. In the first round, candidates are divided into two groups, and the first group receives a test tablet and the second group receives a similar tablet. Blood samples will be taken by the volunteer by the technician immediately after taking the drug, and the preparation steps of the samples, including plasma separation and drug extraction, are performed to analyze the amount of drug.

Participants/Inclusion and exclusion criteria

24 participants will be selected from non-smoking, non-pregnant people without history of heart, kidney and liver disease from both sex (male & female). The ages and BMIs of participant should be in the range of 18-55 and 18-28 respectively.

Intervention groups

Intervention group: single dose Itraconazole Capsules 100mg Kimidarou and control group single dose drugs SPRANOX® 100mg Cps, Janssen-Cilag Pharma Belgium.

Main outcome variables

Determination of blood drug concentration

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20200105046010N15**

Registration date: **2020-11-03, 1399/08/13**

Registration timing: **prospective**

Last update: **2020-11-03, 1399/08/13**

Update count: **0**

Registration date

2020-11-03, 1399/08/13

Registrant information

Name

Javad Shokri

Name of organization / entity

Country

Iran (Islamic Republic of)

Phone

+98 41 3661 4125

Email address

shokri.j@gmail.com

Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2020-11-10, 1399/08/20

Expected recruitment end date

2021-07-11, 1400/04/20

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Pharmacokinetic assessments of Itraconazole capsules in comparison with brand drug SPRANOX

Public title

Itraconazole capsules in-vivo bioequivalence in healthy volunteers iranian

Purpose

Treatment

Inclusion/Exclusion criteria

Inclusion criteria:

General health (liver, heart, kidney) Body Mass Index (BMI) between 18-28 Informed consent Age between 18-28 Both male and female

Exclusion criteria:

Smoking Pregnancy Alcohol & Drug addiction Hypersensitivity to the drug

Age

From **18 years** old to **60 years** old

Gender

Both

Phase

Bioequivalence

Groups that have been masked

- Participant

Sample size

Target sample size: **24**

Randomization (investigator's opinion)

Randomized

Randomization description

Random allocation law is the simplest method of finite randomization. This method represents a large block for the entire sample size; this means that a balance in the number of people assigned to each group will be achieved at the end of the study. For this purpose, first determine a total sample size (24 people), then write the names of the people on paper, and after folding in aluminum foil, pour it into a glass, and then randomly remove the papers and open the first 12 people in group A and The rest are selected as group B.

Blinding (investigator's opinion)

Single blinded

Blinding description

Candidates are not aware of the test drug or brand name. In a one-blind study, information that could distort the test result is hidden from the candidates, but the person in charge of the test is aware of it. Itraconazole and SPRANOX® are removed from their packaging by the executor and placed in similar and coded cans. Volunteers will not be informed about receiving the brand or test dosage form.

Placebo

Not used

Assignment

Parallel

Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee

Tabriz University of Medical Sciences Ethics Committee

Street address

Third floor, Central Bulding of Tabriz University of Medical Sciences, Daneshgah St.

City

Tabriz

Province

East Azarbaijan

Postal code

5166614766

Approval date

2020-09-27, 1399/07/06

Ethics committee reference number

IR.TBZMED.REC.1399.667

Health conditions studied

1

Description of health condition studied

In this study, the disease is not examined. Subject bioequivalence test and reference Itraconazole Capsules studied.

ICD-10 code

ICD-10 code description

Primary outcomes

1

Description

Determination of blood drug concentration.

Timepoint

Sampling times in this study will be 0, 1, 2, 2:30, 3, 3:20, 3:40, 4, 4:20, 4: 40, 5, 6, 8, 10, 12, 24, 48, 72 hours.

Method of measurement

Liquid Chromatography with tandem mass spectroscopy detector

Secondary outcomes

empty

Intervention groups

1

Description

Intervention group: Single dose of Itraconazole Capsules 100 mg Kimidarou Company as a test product.

Category

Treatment - Drugs

2

Description

Control group: Single dose of Itraconazole Capsules with brand drugs SPRANOX® 100mg Cps, Janssen-Cilag Pharma. Belgium.

Category

Treatment - Drugs

Recruitment centers

1

Recruitment center

Name of recruitment center

Simin Baspar Teyf Gostar Company

Full name of responsible person

Javad Shokri

Street address

No.48, Ferdowsi street, Ferdowsi Sq.

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5167874434

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+98 41 3384 2724

Fax

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Shokri.j@gmail.com

Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Chemidarou company

Full name of responsible person

Shima Pakdaman

Street address

3rd km of Tehran-Abali road

City

Tehran

Province

Tehran

Postal code

1746773611

Phone

+98 21 7733 0291

Email

chemidarou@gmail.com

Grant name

Grant code / Reference number

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

No

Title of funding source

Kimidarou 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

Other

Person responsible for general inquiries

Contact

Name of organization / entity

Tabriz University of Medical Sciences

Full name of responsible person

Javad Shokri

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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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

These data are as secure between researcher and related industries.

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

Yes - There is a plan to make this available

Title and more details about the data/document

Only protocol and methods of study are sharable.

When the data will become available and for how long

After finishing of the protocol (Probably 6 months receiving IRCT code)

To whom data/document is available

Pharmaceutical and medical sciences researchers.

Under which criteria data/document could be used

Projects information's for any publications is not allowed.

From where data/document is obtainable

Contact with E-mail of the main researcher.

What processes are involved for a request to access data/document

Personal and academic details and the aim of the request.

Comments