

# 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.

##### City

Tabriz

##### Province

East Azarbaijan

##### Postal code

5167874434

##### Phone

+98 41 3384 2724

##### Fax

##### Email

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

#### Street address

Faculty of Pharmacy, University of Medical Sciences, Daneshgah Street, Tabriz East Azerbaijan

#### City

Tabriz

#### Province

East Azarbaijan

#### Postal code

5166414766

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+98 41 3334 8489

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Shokri.j@gmail.com

## Person responsible for scientific inquiries

### 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**