# Clinical Trial Protocol
# Iranian Registry of Clinical Trials

07 Nov 2026

## In-vivo Bioequivalence Study of Pimozide 4 mg tablets of The Test Drug (Porica®,Tadbir Kalaye jam pharmaceutical co, Iran) in Compared with The Reference Drug (Orap® 4 mg, Janssen. Belguim) In Iranian Healthy Volunteers

## Protocol summary

**Study aim**
In-vivo Bioequivalence Study of Pimozide 4 mg tablets of The Test Drug (Porica®,Tadbir Kalaye jam pharmaceutical co, Iran)

**Design**
Bioequivalence study, crossover, single-blinded, 24 healthy volunteers. Simple randomization was used for randomization.

**Settings and conduct**
The study is a single-blinded (Volunteers), cross-over and fast, and on two series of healthy volunteers. The study will be done in two periods (144h). The interval between these two periods is 1 week. In the first round of the study, the candidates were divided into two groups the first group received a test tablet and the second group received a brand tablet. Blood samples are collected immediately before and after drug administration by volunteers. Then, drug extraction is done and samples are ready for analysis. Sampling is performed in Asr nano company in Tehran.

**Participants/Inclusion and exclusion criteria**
General Health (Liver, Heart, and Kidney), Body Mass Index (18-30), informed consent, Age (18-55years old)

**Intervention groups**
Intervention group 1: (Orap® 4 mg, Janssen. Belguim) tablets as a reference Intervention group 2: (Porica®,Tadbir Kalaye jam pharmaceutical co, Iran) as a test

**Main outcome variables**
Maximum drug concentration, Time to reach maximum drug concentration

## General information

**Reason for update**

**Acronym**

**IRCT registration information**
IRCT registration number: **IRCT20240803062623N8**
Registration date: **2024-10-29, 1403/08/08**
Registration timing: **prospective**

Last update: **2024-10-29, 1403/08/08**
Update count: **0**

**Registration date**
2024-10-29, 1403/08/08

**Registrant information**

**Name**
Mohammad Ali Karkhaneh Yousefi

**Name of organization / entity**
Tadbir Kalaye Jam co.

**Country**
Iran (Islamic Republic of)

**Phone**
+98 21 8866 8700

**Email address**
yousefi@tadbirkala.com

**Recruitment status**
**Recruitment complete**

**Funding source**

**Expected recruitment start date**
2024-12-30, 1403/10/10

**Expected recruitment end date**
2026-01-30, 1404/11/10

**Actual recruitment start date**
empty

**Actual recruitment end date**
empty

**Trial completion date**
empty

**Scientific title**

In-vivo Bioequivalence Study of Pimozide 4 mg tablets of The Test Drug (Porica®,Tadbir Kalaye jam pharmaceutical co, Iran) in Compared with The Reference Drug (Orap® 4 mg, Janssen. Belguim) In Iranian Healthy Volunteers

**Public title**

In-vivo Bioequivalence Study of Pimozide 4 mg tablets of The Test Drug (Porica®,Tadbir Kalaye jam pharmaceutical co, Iran)

**Purpose**

Treatment

**Inclusion/Exclusion criteria**

**Inclusion criteria:**

General Health (Liver, Heart, and Kidney) Body Mass Index (18-30) Informed consent Age (18-55years old)

**Exclusion criteria:**

Smoking History of cardiovascular disease History of liver and kidney disease Alcoholism and Narcoticism History of allergy to Pimozide

**Age**

From **18 years** old to **55 years** old

**Gender**

Both

**Phase**

Bioequivalence

**Groups that have been masked**

- Participant

**Sample size**

Target sample size: **24**

More than 1 sample in each individual

Number of samples in each individual: **40**

Blood sample

**Randomization (investigator's opinion)**

Randomized

**Randomization description**

People in the mentioned age group are invited to participate through the advertisement. People are then checked for health and healthy volunteers are identified. Each candidate is assigned a number from 1 to 24. The numbers are written on a plastic ball poured into a container and mixed. The balls are then removed randomly from the container. The first 12 no.s are considered as (first sequence: test medicine ) and the second 12 no.s are considered as (second sequence: originator brand recipient). The volunteers don't have any information about taking the test drug or brand drug.

**Blinding (investigator's opinion)**

Single blinded

**Blinding description**

This study is a single-blinded clinical trial (volunteers). Test and Originator brand's tablets 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**

Crossover

**Other design features**

## Secondary Ids

empty

## Ethics committees

### 1

**Ethics committee**

**Name of ethics committee**

Ethics committee of Tehran University of Medical Sciences

**Street address**

5th floor,No. 60, Mollasadra Ave, Vanak Sq

**City**

Tehran

**Province**

Tehran

**Postal code**

1435793175

**Approval date**

2023-01-22, 1401/11/02

**Ethics committee reference number**

IR.TUMS.TIPS.REC.1401.104

## Health conditions studied

### 1

**Description of health condition studied**

This study is performed on healthy volunteers and drug concentration in plasma is determined.

**ICD-10 code**

**ICD-10 code description**

## Primary outcomes

### 1

**Description**

Drug plasma concentration

**Timepoint**

0، 0.5، 1، 2، 3، 4 ، 5، 6 ، 7، 8، 10 ، 12 ، 24 ، 30 ، 36 ، 48 ، 72 ، 96 ، 120 ، 144 h after drug administration

**Method of measurement**

Liquid chromatography (mass spectrometry)

## Secondary outcomes

### 1

**Description**

Time to reach maximum plasma concentration

**Timepoint**

After intervention

**Method of measurement**

Time to reach the maximum drug concentration in plasma is recorded.

### 2

**Description**

Extent of absorption

**Timepoint**

After intervention

**Method of measurement**

Calculation of area under curve of concentration -time

## Intervention groups

### 1

**Description**

Intervention group: single dose, one oral tablets (Orap® 4 mg, Janssen. Belguim) as a reference product. after washout period, the volunteers received Pimozide 4 mg (Porica®,Tadbir Kalaye jam pharmaceutical co, Iran)

**Category**

Treatment - Drugs

### 2

**Description**

Intervention group: Single dose, one oral Pimozide 4 mg tablet (Porica® Tadbir Kalaye jam pharmaceutical co, Iran) as test product. after washout period, the volunteers received (Orap® 4 mg, Janssen. Belguim)

**Category**

Treatment - Drugs

## Recruitment centers

### 1

**Recruitment center**

**Name of recruitment center**

Asr Nano company

**Full name of responsible person**

Mohammad Ali Karkhaneh Yousefi

**Street address**

Asr Nano company, Polymer research institute, Pajuhesh boulevard, Tehran

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**Postal code**

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**Email**

yousefi@tadbirkala.com

## Sponsors / Funding sources

### 1

**Sponsor**

**Name of organization / entity**

Tadbir Kala Jam

**Full name of responsible person**

Mohammad Ali Karkhane Yosefi

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**Email**

n.mohammadi@tadbirkala.com

**Grant name**

**Grant code / Reference number**

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

No

**Title of funding source**

Tadbir Kala Jam

**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**

Tadbir Kalaye Jam Co.

**Full name of responsible person**

Mohammad Ali Karkhaneh Yousefi

**Position**

Medical Manager

**Latest degree**

Medical doctor

**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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**Full name of responsible person**
Mohammad Ali Karkhaneh Yousefi

**Position**
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**Latest degree**
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**Other areas of specialty/work**
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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 researchers 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**
No - There is not a plan to make this available