Clinical Trial Protocol
Iranian Registry of Clinical Trials

09 Nov 2026

In-vivo bioequivalence study of Itraconazole 100 mg capsule of the test drug manufactured by Arian Salamat Sina pharmacutical company in compared with the reference drug Sporanox 100 mg capsule

Protocol summary

Study aim

In-vivo bioequivalence study of Itraconazole 100 mg capsule of the test drug manufactured by Arian Salamat Sina pharmacutical company in compared with the reference drug Sporanox 100 mg capsule

Design

Bioequivalence study, Cross-over design, Single dose, Single-blinded, 24 healthy volunteers, Two period, two week wash out period, Simple randomization method will be used.

Settings and conduct

This single-blind, two-period crossover study was conducted on two groups of healthy volunteers at Radin Shimi Company in Tabriz. Each period lasted 72hours, with a two -week washout interval between them. In the first period, based on computer-generated randomization, Group 1 received the reference drug while Group 2 received the test drug. In the second period, the treatments were switched. The study was single-blinded, meaning that participants were unaware whether they received the test or reference drug during either sampling period.

Participants/Inclusion and exclusion criteria

Inclusion criteria: No history of heart, kidney & liver disease. The ages and BMIs of participant should be in the range of 18-55 and 18-30 respectively. Exclusion criteria: Smoking, Alcohol and drug addiction, History of allergy to drug, Pregnancy.

Intervention groups

Intervention group one receivesItraconazole 100 mg capsule of the test drug manufactured by Arian Salamat Sina pharmacutical company in the first round, and in the second round, after two-week washout period, the drug Sporanox 100 mg . Intervention group No.2 receives the drugs in the switched order.

Main outcome variables

The concentration of the drug in blood, Time to reach maximum blood concentration, Extent of absorption

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20240804062647N69**
Registration date: **2026-09-17, 1405/06/26**
Registration timing: **prospective**

Last update: **2026-09-17, 1405/06/26**
Update count: **0**

Registration date

2026-09-17, 1405/06/26

Registrant information

Name

Massoud Amanlou

Name of organization / entity

Country

Iran (Islamic Republic of)

Phone

+98 21 6695 9067

Email address

amanlou@tums.ac.ir

Recruitment status

recruiting

Funding source

Expected recruitment start date

2026-10-07, 1405/07/15

Expected recruitment end date

2027-10-07, 1406/07/15

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date
empty

Scientific title
In-vivo bioequivalence study of Itraconazole 100 mg capsule of the test drug manufactured by Arian Salamat Sina pharmacutical company in compared with the reference drug Sporanox 100 mg capsule

Public title
In-vivo bioequivalence study of Itraconazole 100 mg capsule of the test drug manufactured by Arian Salamat Sina pharmacutical company

Purpose
Treatment

Inclusion/Exclusion criteria
Inclusion criteria:
General health (liver, heart, kidney) of volunteers Informed consent form Body mass index range (18-30) Age between18-55
Exclusion criteria:
Smoking Having a history of cardiovascular disease Having a history of liver & kidney disease Having a Alcohol & Drug addiction Having a hypersensitivity to the drug Pregnancy

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: **34**
Blood sample

Randomization (investigator's opinion)
Randomized

Randomization description
At first, all of the volunteers are evaluated for meeting inclusion criteria, selecting the final participants. Each volunteer is randomly assigned to a number between 1 and 24 using simple randomization, receiving an identification card containing the assigned number. Next, at first study period, volunteers with even numbers will receive the reference drug and volunteers with odd numbers will receive the test drug. In the second period, the formulations are switched in a cross-over design. The formulation assignment to the subjects is done randomly, with the participants and the trial staff not aware the formulation administered, thus, providing the blinding situation for all stages of the study.

Blinding (investigator's opinion)
Single blinded

Blinding description
This study is a single-blind (participant) clinical trial Itraconazole 100 mg capsule of the test drug manufactured by Arian Salamat Sina pharmacutical company and the original brand are removed from their packaging by the operator and placed in identical, coded cans. Volunteers are unaware of the type of drug or test they are receiving.

Placebo
Not used

Assignment
Crossover

Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee
Name of ethics committee
Tabriz University of Medical Sciences ethics committe
Street address
International Relations Office, No 2 Central Building, Tabriz University of Medical Sciences, Golgasht Street,
City
Tabriz
Province
East Azarbaijan
Postal code
5174864471

Approval date
2026-08-24, 1405/06/02

Ethics committee reference number
IR.TBZMED.REC.1405.372

Health conditions studied

1

Description of health condition studied
This study is performed on healthy volunteers.

ICD-10 code

ICD-10 code description

Primary outcomes

1

Description
The concentration of the drug in blood

Timepoint
0 , 1 , 1.5 , 2 , 2.5 , 3 , 3.5 , 4 , 4.5 , 5 , 5.5 , 6 , 8 , 10 , 24 , 48 , 72 h after drug

Method of measurement
Liquid Chromatography with Mass-Mass Detector

Secondary outcomes

1

Description

Time to reach maximum blood concentration

Timepoint

After intervention

Method of measurement

The time to reach the maximum drug concentration in blood is recorded. This is done after completing the device analysis of the samples and through the WinNonLine software developed by Phoenix Company.

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: Intervention group: single dose of Itraconazole 100 mg capsule of the test drug manufactured by Arian Salamat Sina pharmacutical company , in the first period. Cross-over design with two week wash out period.After two week in the second period, a single dose of Sporanox 100 mg

Category

Treatment - Drugs

2

Description

Intervention group: Single-dose of Sporanox 100 mg, in the first period. Cross-over design with two week wash out period. After two week in the second period, a single dose of Itraconazole 100 mg capsule of the test drug manufactured by Arian Salamat Sina pharmacutical company

Category

Treatment - Drugs

Recruitment centers

1

Recruitment center

Name of recruitment center

Radin laboratory

Full name of responsible person

Bahram Ataii

Street address

No.22, first floor, Moalem st., Abureihan St

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Tabriz

Province

East Azarbaijan

Postal code

5154995671

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ataii.bahram@gmail.com

Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Arian Salamat Sina

Full name of responsible person

Shahruzi Habibalah

Street address

No. 9, Bahar Bldg., Abbas Shirazi St., Vanak, Tehran

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Tehran

Province

Tehran

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1435883346

Phone

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Email

info@ariansalamat.com

Grant name

Grant code / Reference number

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

Yes

Title of funding source

Arian Salamat Sina

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

Tehran University of Medical Sciences

Full name of responsible person

Massoud Amanlou

Position

Academic staff and full-time professor of the Faculty of Pharmacy

Latest degree

Ph.D.

Other areas of specialty/work

Medical Pharmacy

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Phone
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Fax
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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