Clinical Trial Protocol
Iranian Registry of Clinical Trials

30 May 2026

Bioequivalence study of aripiprazole 5 mg tablet from Kimidaro Pharmaceutical Company compared to aripiprazole 5 mg sample from Otsuka Pharmaceutical Netherlands B.V. United Kingdom on healthy volunteers

Protocol summary

Study aim

Bioequivalence study of aripiprazole 5 mg tablet of Kimidarou pharmaceutical company in comparison with the same sample made by Otsuka Pharmaceutical Netherlands B.V company in England on healthy volunteers.

Design

The present clinical trial includes the bioequivalence study of aripiprazole 5 mg tablets produced by Kimidarou Pharmaceutical Company in comparison with the sample of aripiprazole 5 mg produced by Otsuka Pharmaceutical Netherlands B.V., United Kingdom, after administration to 24 healthy human volunteers, in two intervention groups, in a cross-over manner. , is not blinded and non-randomized.

Settings and conduct

The study is carried out at Nik Azma Pars Alborz company located in Mahdasht Karaj, Imam Khomeini Blvd., Azadegan Square, No. 419. The study is cross-blinded, including two stages (oral intake of a 5 mg aripiprazole tablet per study and in total 2 times) with a seven-week washing period on 24 fasting healthy volunteers. Blood samples are taken from the volunteers at certain intervals of drug consumption, and then the amount of aripiprazole in plasma is determined by liquid chromatography-mass spectrometry.

Participants/Inclusion and exclusion criteria

Inclusion criteria: healthy volunteers between the ages of 18 and 65 should be non-smokers. Exclusion criteria: volunteers with blood pressure less than 90 over 60 mm Hg or higher than 140 over 90 mm Hg.

Intervention groups

The study includes two stages as intervention 1: It includes the oral intake of Aripiprazole 5 mg tablets manufactured by Kimidarou Pharmaceutical Company in Iran and Intervention 2: The oral intake of Aripiprazole 5 mg tablets manufactured by Otsuka Pharmaceutical Netherlands B.V. in the United Kingdom. This study will be repeated on fasting volunteers in a cross-sectional manner with an interval of seven weeks.

Main outcome variables

Maximum plasma concentration

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20230222057495N6**
Registration date: **2023-06-11, 1402/03/21**
Registration timing: **registered_while_recruiting**

Last update: **2023-06-11, 1402/03/21**
Update count: **0**

Registration date

2023-06-11, 1402/03/21

Registrant information

Name

Monireh Jalalipour

Name of organization / entity

Nikazma Pars Alborz company

Country

Iran (Islamic Republic of)

Phone

+98 26 3731 8748

Email address

info@naplab.ir

Recruitment status

Recruitment complete

Funding source

Expected recruitment start date
2023-05-22, 1402/03/01
Expected recruitment end date
2023-11-22, 1402/09/01
Actual recruitment start date
empty
Actual recruitment end date
empty
Trial completion date
empty

Scientific title
Bioequivalence study of aripiprazole 5 mg tablet from Kimidaro Pharmaceutical Company compared to aripiprazole 5 mg sample from Otsuka Pharmaceutical Netherlands B.V. United Kingdom on healthy volunteers

Public title
Bioequivalence study of aripiprazole 5 mg tablet
Purpose
Other
Inclusion/Exclusion criteria
Inclusion criteria:
Healthy volunteers aged between 18 and 65 years All candidates must be non-smokers Body mass index less than 30 kg per square meter
Exclusion criteria:
Blood pressure less than 90 over 60 mm Hg or more than 140 over 90 mm Hg Consumption of any drugs, alcohol or tobacco products within 2 weeks before receiving the drug
Age
From **18 years** old to **65 years** old
Gender
Both

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: **34**

Randomization (investigator's opinion)
Not randomized
Randomization description
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
Research Institute of Pharmaceutical Sciences, Tehran University of Medical Sciences
Street address
Institute of Pharmaceutical Sciences, Faculty of Pharmacy, Tehran University of Medical Sciences, Porsina Street
City
Tehran
Province
Tehran
Postal code
1417613151
Approval date
2023-06-10, 1402/03/20
Ethics committee reference number
IR.TUMS.TIPS.REC.1402.039

Health conditions studied

1

Description of health condition studied

ICD-10 code
ICD-10 code description

Primary outcomes

1

Description
Maximum plasma concentration of Aripiprazole
Timepoint
Before taking the drug and: 0.5, 1, 1.5, 2, 2.5, 3, 3.5, 4, 4.5, 5, 6, 8, 10, 24, 48 and 72 hours after taking the drug
Method of measurement
Liquid chromatography-mass spectrometry

Secondary outcomes

empty

Intervention groups

1

Description
Intervention group 1: includes the oral consumption of a 5 mg aripiprazole tablet manufactured by Kimidarou Pharmaceutical Company of Iran on 24 healthy fasting volunteers. 5 ml of blood at time intervals before taking the drug and: 0.5, 1, 1.5, 2, 2.5, 3, 3.5, 4, 4.5, 5, 6, 8, 10, 24, 48 and 72 hours after taking the drug It is taken from volunteers. The cross-over study consists of two phases (oral administration of a 5 mg aripiprazole tablet in each study and 2 times in total) with a seven-week washout

period (when the drug is completely out of your blood). Aripiprazole plasma concentration is determined by liquid chromatography-mass spectrometry method. The analysis of the results will be based on ANOVA and t-test statistical methods.

Category

Other

2

Description

Intervention group 2: includes the oral consumption of a 5 mg aripiprazole tablet manufactured by Otsuka Pharmaceutical Netherlands B.V. in the United Kingdom on 24 fasting healthy volunteers. 5 ml of blood at time intervals before taking the drug and: 0.5, 1, 1.5, 2, 2.5, 3, 3.5, 4, 4.5, 5, 6, 8, 10, 24, 48 and 72 hours after taking the drug It is taken from volunteers. The cross-over study consists of two phases (oral administration of a 5 mg aripiprazole tablet in each study and 2 times in total) with a seven-week washout period (when the drug is completely out of your blood). Aripiprazole plasma concentration is determined by liquid chromatography-mass spectrometry method. The analysis of the results will be based on ANOVA and t-test statistical methods.

Category

Other

Recruitment centers

1

Recruitment center

Name of recruitment center
Nik Azma Pars Alborz Laboratory
Full name of responsible person
Monireh Jalalipour
Street address
No. 419, Azadegan Square, Imam Khomeini Bouevard
City
Mahdasht Karaj
Province
Alborz
Postal code
3188913179
Phone
+98 26 3731 8748
Email
info@naplab.ir

Sponsors / Funding sources

1

Sponsor

Name of organization / entity
Chemidarou Pharmaceutical Company
Full name of responsible person
Mojgan Aghajani
Street address
after Saipa repair shop, Kilometer 3,Tehran-Abali road, Sorkhe Hesar, District 13
City
Tehran
Province
Tehran
Postal code
1746773611
Phone
+98 21 7733 0291
Email
office@chemidarou.com

Grant name

Grant code / Reference number

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

Yes

Title of funding source

Chemidarou 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

Industry

Person responsible for general inquiries

Contact

Name of organization / entity
Nik Azma Pars Alborz laboratory
Full name of responsible person
Monireh Jalalipour
Position
Responsible Pharmacist
Latest degree
Ph.D.
Other areas of specialty/work
Medical Pharmacy
Street address
No. 419, Azadegan Square, Imam Khomeini Boulevard
City
Mahdasht Karaj
Province
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Person responsible for scientific inquiries

Contact

Name of organization / entity
Nik Azma Pars Alborz laboratory
Full name of responsible person

Monireh Jalalipour

Position
Responsible Pharmacist

Latest degree
Ph.D.

Other areas of specialty/work
Medical Pharmacy

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Person responsible for updating data

Contact

Name of organization / entity
Nik Azma Pars Alborz laboratory

Full name of responsible person
Monireh Jalalipour

Position
Responsible pharmacist

Latest degree
Ph.D.

Other areas of specialty/work
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Sharing plan

Deidentified Individual Participant Data Set (IPD)
Undecided - It is not yet known if there will be 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
Undecided - It is not yet known if there will be 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
Undecided - It is not yet known if there will be a plan to make this available

Data Dictionary
Undecided - It is not yet known if there will be a plan to make this available