

# Clinical Trial Protocol

## Iranian Registry of Clinical Trials

30 May 2026

### Bioequivalence study of aripiprazole 5 mg tablet from Kimidarou 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 Kimidar 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**

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**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**

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**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

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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**

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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**

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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)**

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