Clinical Trial Protocol
Iranian Registry of Clinical Trials

30 May 2026

Bioequivalence evaluation of Aripiperazole 5 mg manufactured by Actover company

Protocol summary

Study aim
Bioequivalence evaluation of Aripiperazole 5 mg manufactured by Actover company

Design
The number of volunteers is 24 people who are divided into 2 groups of control and intervention. The study is double blind non randomized. Each candidate uses the test drug in the first round and the reference drug 42 days after the first round,

Settings and conduct
Aripiprazole manufactured by Actovorco and Otsuka Company will be administered with an interval of 42 days. At each time, the amount of 3 cc of blood will be taken.

Participants/Inclusion and exclusion criteria
Inclusion: 18 to 45 years old Body mass index: 18.5 to 24.9 weight in kg/(height in meter) Able to communicate effectively Do not take any chronic or acute medication for at least 1 week before the start of the study No history of diseases Exclusion: History of allergic responses Have significant diseases Smokers History or evidence of drug dependence or of alcoholism or of moderate alcohol use Volunteers who have received a known investigational drug within 90 days prior to the initial dose of study drug

Intervention groups
Intervention group: Prescription of Aripiperazole 5 mg manufactured by Actover company from Iran in the first round Control group: Prescription of Aripiperazole 5 mg Tablet manufactured by Otsuka company from America 42 days after first dose.

Main outcome variables
Maximum concentration; Time to get Maximum concentration; Area under the curve

General information

Reason for update

Acronym
BEA

IRCT registration information
IRCT registration number: **IRCT20200625047913N7**
Registration date: **2021-09-07, 1400/06/16**
Registration timing: **registered_while_recruiting**

Last update: **2021-09-07, 1400/06/16**
Update count: **0**

Registration date
2021-09-07, 1400/06/16

Registrant information

Name
Tayebeh Ghari

Name of organization / entity
Hezareh Sevom Futuristic Pharmacist Company

Country
Iran (Islamic Republic of)

Phone
+98 21 8865 2343

Email address
info@hezareh-co.com

Recruitment status
Recruitment complete

Funding source

Expected recruitment start date
2021-08-31, 1400/06/09

Expected recruitment end date
2021-11-30, 1400/09/09

Actual recruitment start date
empty

Actual recruitment end date
empty

Trial completion date
empty

Scientific title
Bioequivalence evaluation of Aripiperazole 5 mg manufactured by Actover company

Public title
Bioequivalence evaluation of Aripiperazole 5 mg manufactured by Actover company
Purpose
Treatment
Inclusion/Exclusion criteria
Inclusion criteria:
18 to 45 years old Sex: Males and/or non-pregnant, non-lactating females Body mass index: 18.5 to 24.9 weight in kg/(height in meter)g Able to communicate effectively with study personnel and willingness to follow the protocol requirements as evidenced by written informed consent A physical examination with no clinically significant finding and laboratory normal tests Do not take any chronic or acute medication for at least 1 week before the start of the study No history of diseases affecting the pharmacokinetic processes of the dru
Exclusion criteria:
History of allergic responses to Aripiperazole or other related drugs, or any of its formulation ingredients Have significant diseases (which might compromise the haemopoeitic, gastrointestinal, renal, hepatic, cardiovascular, respiratory, central nervous system, diabetes, psychosis or any other body system) or clinically significant abnormal findings during screening Smokers who smoke 10 or more cigarettes per day or 20 or more biddies per day or those who cannot refrain from smoking during the study period History or evidence of drug dependence or of alcoholism or of moderate alcohol use، History of difficulty with donating blood or difficulty in accessibility of veins Volunteers who have received a known investigational drug within five elimination half life of the administered drug prior to the initial dose of study drug or who have participated in a clinical drug study or bioequivalence study within 90 days prior to the initial dose of study drug, whichever is greater Found positive in urine test for drugs of abuse done before check-in of period History of difficulty in swallowing, or of any gastrointestinal disease which could affect drug absorption
Age
From **18 years** old to **45 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: **2**
A test and reference drug will be administrated to the volunteers in first week and 24 days later.
Randomization (investigator's opinion)
Not randomized
Randomization description
Blinding (investigator's opinion)
Single blinded
Blinding description
Regarding the study of the bioequivalence of aripiprazole, the participating volunteers do not know the type of medication they were receiving at each time. Candidates are given one dose of the test drug and then the reference drug will given them 42 days later. Candidates are not aware of which drug they are taking each time. The main researcher of the project, the doctor and the nurse are knowing about the type of medicine that the volunteer takes at each time.
Placebo
Not used
Assignment
Crossover
Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee
Name of ethics committee
Ethics committee of institute of pharmaceutical science of Tehran University of Medical Sciences
Street address
16 Azar Avenue, Tehran University of Medical Sciences, Faculty of Pharmacy, The Institute of Pharmaceutical Sciences, 2nd floor, Unit 1-219, Tehran- Iran.
City
Tehran
Province
Tehran
Postal code
۱۴۱۷۶۱۴۴۱۱
Approval date
2021-08-16, 1400/05/25
Ethics committee reference number
IR.TUMS.TIPS.REC.1400.103

Health conditions studied

1

Description of health condition studied
SCHIZOPHRENIA
ICD-10 code
ICD-10 code description

Primary outcomes

1

Description
Maximum plasma concentration
Timepoint
0، 5/0، 1، 5/1، 2، 5/2، 3، 4، 5، 6، 7، 8، 10، 12، 24، 32، 48، 72 Hour
Method of measurement

Liquid chromatography mass mass (lc ms ms)

2

Description
area under the curve
Timepoint
0، 5/0، 1، 5/1، 2، 5/2، 3، 4، 5، 6، 7، 8، 10، 12، 24، 32، 48، 72 hr
Method of measurement
Liquid chromatography mass mass (lc ms ms)

3

Description
Time take to reach maximum plasma concentration
Timepoint
0، 5/0، 1، 5/1، 2، 5/2، 3، 4، 5، 6، 7، 8، 10، 12، 24، 32، 48، 72 hr
Method of measurement
Clock

Secondary outcomes

empty

Intervention groups

1

Description
Aripiperazole 5 mg Tablet manufactured by Actoverco pharmaceutical company from Iran will administrate in the first week.
Category
Other

2

Description
Control group: Prescription of Aripiperazole 5 mg manufactured by Otsuka company from America in the first day of study
Category
Other

Recruitment centers

1

Recruitment center
Name of recruitment center
Hezareh Sevom Futuristic Pharmacist Company
Full name of responsible person
Tayebeh Ghari
Street address
Unit 4, No. 81, Babak Bahrami st, After Zafar st, Tehran, Iran.
City
تهران
Province
Tehran
Postal code
1968655815
Phone
+98 21 8865 2343
Fax
+98 21 8820 8678
Email
info@hezareh-co.com

Sponsors / Funding sources

1

Sponsor
Name of organization / entity
Hezareh Sevom Futuristic Pharmacist
Full name of responsible person
Tayebeh Ghari
Street address
Unit 4, No 81, Babak Bahrami st, After Zafar st, Tehran, Iran.
City
Tehran
Province
Tehran
Postal code
1968655815
Phone
+98 21 8865 2343
Email
info@hezareh-co.com
Grant name
Grant code / Reference number
Is the source of funding the same sponsor organization/entity?
Yes
Title of funding source
Hezareh Sevom Futuristic Pharmacist
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
Alborze University of Medical Sciencesو School of Pharmacy
Full name of responsible person
Faranak Salmannejad
Position
Assistant Professor
Latest degree
Ph.D.
Other areas of specialty/work

Medical Pharmacy

Street address

Alborze School of pharmacy, near Bahonar Hospital, Vali-e-asr st, Shora Blv,Karaj.

City

Karaj

Province

Alborz

Postal code

3154686689

Phone

+98 26 3256 7175

Email

salmannejad.f@gmail.com

Person responsible for scientific inquiries

Contact

Name of organization / entity

Alborze University of Medical Sciences، School of Pharmacy

Full name of responsible person

Faranak Salmannejad

Position

Assistant Professor

Latest degree

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Other areas of specialty/work

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+98 26 3256 7175

Email

salmannejad.f@gmail.com

Person responsible for updating data

Contact

Name of organization / entity

Alborze University of Medical Sciences، School of Pharmacy

Full name of responsible person

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Position

Assistant Professor

Latest degree

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Postal code

3154686689

Phone

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Email

salmannejad.f@gmail.com

Sharing plan

Deidentified Individual Participant Data Set (IPD)

Yes - There is a plan to make this available

Study Protocol

Yes - There is a plan to make this available

Statistical Analysis Plan

Yes - There is a plan to make this available

Informed Consent Form

Yes - There is a plan to make this available

Clinical Study Report

Yes - There is 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

All data is potentially shareable after unidentified individuals.

When the data will become available and for how long

Access period starts from March 1400

To whom data/document is available

People working in industry and academia

Under which criteria data/document could be used

People working in industry and academia

From where data/document is obtainable

Sending email to info@hezareh-co.com - Sending fax to 00982188208678 - Calling to 00982188652343 - Responsible person: Tayebeh Ghari

What processes are involved for a request to access data/document

Sending email to info@hezareh-co.com Request evaluation during 1 week Sending data during 1 week

Comments