Clinical Trial Protocol
Iranian Registry of Clinical Trials

16 Sep 2026

Bioequivalence evaluation of Methylphenidate Tablet 10 mg of Karen Pharmaceutical company

Protocol summary

Study aim
Bioequivalence study of methylphenidate manufactured by Karen pharmaceutical company
Design
Clinical trials of 24 volunteers
Settings and conduct
After selecting the volunteers, methylphenidate drug manufactured by Karen and Novartis will be prescribed to them orally in two doses with an interval of 7 days. For example, if in the first period, the volunteer received the drug manufactured by Karen, in the next turn, the volunteer will receive the drug manufactured by Novartis. Each time the amount of 6 cc of blood before drug administration and at times of 0 ،0.33، 0.66، 1، 1.33، 1.66، 2، 2.5، 3، 3.5، 4، 5، 6، 8، 10، 12 hour after the medication is prescribed. Samples were collected in Anticoagulant tube collection tubes. The tubes were centrifuged and plasma samples were stored at -80 ℃ . Finally, the amount of drug in each sample is determined by Lc Mass Mass equipment.
Participants/Inclusion and exclusion criteria
Healthy volunteers, no history of diseases affecting the pharmacokinetic processes of the drug, no chronic or acute use of any drug at least 1 week before starting the study
Intervention groups
Volunteers will divided in two groups: On the first week, group one will receive methylphenidate manufactured by Karen pharmaceutical company and group number two will receive methylphenidate manufactured by Novartis pharmaceutical company . On the second week, group number one will receive methylphenidate manufactured by Novartis pharmaceutical company and group number two will receive methylphenidate manufactured by Karen pharmaceutical company (cross over)
Main outcome variables
Maximum plasma concentration; area under the curve; the time take to reach maximum plasma concentration

General information

Reason for update
Acronym
IRCT registration information
IRCT registration number: **IRCT20200625047913N9**
Registration date: **2023-01-16, 1401/10/26**
Registration timing: **registered_while_recruiting**

Last update: **2023-01-16, 1401/10/26**
Update count: **0**
Registration date
2023-01-16, 1401/10/26

Registrant information
Name
Tayebeh Ghari
Name of organization / entity
Hezareh Sevom Futuristic Pharmacist Company
Country
Iran (Islamic Republic of)
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+98 21 8865 2343
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Recruitment status
Recruitment complete
Funding source

Expected recruitment start date
2023-01-11, 1401/10/21
Expected recruitment end date
2023-01-19, 1401/10/29
Actual recruitment start date
empty
Actual recruitment end date
empty
Trial completion date
empty

Scientific title
Bioequivalence evaluation of Methylphenidate Tablet 10 mg of Karen Pharmaceutical company

Public title
Bioequivalence evaluation of Methylphenidate Tablet 10 mg of Karen Pharmaceutical company
Purpose
Health service research
Inclusion/Exclusion criteria
Inclusion criteria:
18 to 45 years old Sex: Males and/or non-pregnant, non-lactating females BMI: 18.5 to 24.9 weight in kg/(height in meter) 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 drug
Exclusion criteria:
History of allergic responses to Methylphenidate 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 History or presence of bronchial asthma 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
No information
Sample size
Target sample size: **24**
Randomization (investigator's opinion)
Randomized
Randomization description
A test and reference drug will be administrated to the volunteers in first week and one week after that. Volunteers do not know which medication they are taking each week.
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
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
تهران
Province
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Postal code
۱۴۱۷۶۱۴۴۱۱
Approval date
2023-01-08, 1401/10/18
Ethics committee reference number
IR.TUMS.TIPS.REC.1401.100

Health conditions studied

1

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

Primary outcomes

1

Description
Plasma concentration
Timepoint
0 ،0.33، 0.66، 1، 1.33، 1.66، 2، 2.5، 3، 3.5، 4، 5، 6، 8، 10، 12 hour
Method of measurement
LC ms ms

Secondary outcomes

empty

Intervention groups

1

Description
Intervention group: methylphenidate 10 mg tablets made by Karen pharmaceutical company from Iran will prescribe in the first week at fast condition and blood samples will draw in determined intervals.

Category
N/A

2

Description
Control group: methylphenidate 10 mg tablets made by Novartis pharmaceutical company from Iran will prescribe in the first week at fast condition and blood samples will draw in determined intervals.

Category
N/A

Recruitment centers

1

Recruitment center

Name of recruitment center
Hezareh Sevom Futuristic Pharmacist Company

Full name of responsible person
Tayebeh Ghari

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Unit 4, No. 81, Babak Bahrami st, After Zafar st, Tehran, Iran.

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Sponsors / Funding sources

1

Sponsor

Name of organization / entity
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Full name of responsible person
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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

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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
No - There is not 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
from 2023
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/sending data
Comments