

# Clinical Trial Protocol

## Iranian Registry of Clinical Trials

09 Jun 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 °C . 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 be divided into 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 taken 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)

##### Phone

+98 21 8865 2343

##### Email address

info@hezareh-co.com

##### 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 haemopoietic, 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**

Tehran

**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**

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**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

#### 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

Tayebehghari@gmail.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

تهران

#### Province

Tehran

#### Postal code

1968655815

#### Phone

+98 21 8865 2343

#### Email

Tayebehghari@gmail.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 Sciences, 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**

Ph.D.

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**Person responsible for updating data****Contact****Name of organization / entity**

Alborze University of Medical Sciences, School of Pharmacy

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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**

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**