

Clinical Trial Protocol

Iranian Registry of Clinical Trials

19 Sep 2026

Bioequivalence study of Riluzole Tablet 50 mg

Protocol summary

Study aim

Bioequivalence study of Riluzole Tablet 50 mg

Design

Clinical trials of single blind design of 48 volunteers

Settings and conduct

After selecting the volunteers, Riluzole drug manufactured by Hooger Daru Company from Iran and by Sanofi Aventis Company of France will be prescribed to them orally in two doses with an interval of 7 days. For example, if in the first period of the drug administration, the volunteer received the drug manufactured by Hooger Darura, in the next turn, the volunteer will receive the drug manufactured by Sanofi Aventis. Each time the amount of 6 cc of blood before drug administration and at times of 0.25, 0.5, 0.75, 1, 1.25, 1.5, 2, 4, 6, 8, 12, 16, It will be taken from the volunteers 24 and 48 hours after the medication is prescribed. The next sampling will 7 days later. In the second time, similar to the first time of drug administration, blood sampling will be done. In the next step, the serum and plasma of each sample are separated by centrifuge and the amount of drug in each sample is determined by liquid extraction method and using Lc Mass Mass. The study will be done in Hezareh Sevom Futuristic Pharmacist company

Participants/Inclusion and exclusion criteria

Healthy volunteers with 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 Riluzole of Hoger Daru company and group number two will receive Riluzole of Sanofi Aventis. On the second week, group number one will receive Riluzole of Sanofi Aventis and group number two will receive Riluzole of Hoger Daru company (cross over)

Main outcome variables

Maximum plasma concentration_g; area under the curve; the time take to reach maximum plasma concentration

General information

Reason for update

Acronym

BSRT

IRCT registration information

IRCT registration number: **IRCT20200625047913N1**

Registration date: **2020-09-18, 1399/06/28**

Registration timing: **registered_while_recruiting**

Last update: **2020-09-18, 1399/06/28**

Update count: **0**

Registration date

2020-09-18, 1399/06/28

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

2020-09-12, 1399/06/22

Expected recruitment end date

2020-10-13, 1399/07/22

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Bioequivalence study of Riluzole Tablet 50 mg

Public title

Bioequivalence study of Riluzole Tablet 50 mg

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 Riluzole 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 I. 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: **48**

Randomization (investigator's opinion)

N/A

Randomization description**Blinding (investigator's opinion)**

Single blinded

Blinding 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.

Placebo

Not used

Assignment

Crossover

Other design features**Secondary Ids**

empty

Ethics committees**1****Ethics committee****Name of ethics committee**

Ethics committee of Tehran University of Medical Sciences

Street address

First floor, Building number 1 of school of medicine, North Door of the University, Poursina St, Ghods St, Enghelab St, Tehran. Iran

City

Tehran

Province

Tehran

Postal code

1417653911

Approval date

2020-08-27, 1399/06/06

Ethics committee reference number

IR.TUMS.MEDICINE.REC.1399.368

Health conditions studied**1****Description of health condition studied**

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ICD-10 code

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ICD-10 code description

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Primary outcomes**1****Description**

Plasma concentration

Timepoint

25/0, 5/0, 75/0, 1, 25/1, 5/1, 2, 4, 6, 8, 12, 16, 24, 48 hr

Method of measurement

HPLC/LC Mass Mass

Secondary outcomes

empty

Intervention groups

1

Description

Prescription of Riluzole 50 mg tablets made by Hoogar Daru company from Iran in the first week

Category

Other

2

Description

Control group: Prescription of Riluzole 50 mg tablets made by Sanofi Aventis from France in the Second week

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.

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1968655815

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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.

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1968655815

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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 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.

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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.

Other areas of specialty/work

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Person responsible for updating data

Contact

Name of organization / entity

Alborze University of Medical Sciences, School of
Pharmacy

Full name of responsible person

Faranak Salmannejad

Position

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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

Yes - There is 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

from 2021

To whom data/document is available

People working in industry and academia

Under which criteria data/document could be used

Specify the exact purpose of the requested
documentation

From where data/document is obtainable

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

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

Sending email to info@hezareh-co.com/ request
evaluation/sending data

Comments