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؛ 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 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 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
--
ICD-10 code
--
ICD-10 code description
--

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.
City
Tehran
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 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.

Other areas of specialty/work
Medical Pharmacy

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

City
Karaj

Province
Alborz

Postal code
3154686689

Phone
+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
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

Fax
+98 26 3256 7176

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
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: 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