Clinical Trial Protocol
Iranian Registry of Clinical Trials

09 Jun 2026

In- Vivo Bioequivalence study of Levetiracetam tablet 1000mg Cobel Darou (LEVEBEL 1000mg) with brand drugs (KEPPRA 1000mg UCB Pharma, Belgium) in Iranian healthy volunteers

Protocol summary

Study aim
In- Vivo Bioequivalence study of Levetiracetam tablet 1000mg Cobel Darou (LEVEBEL 1000mg) with brand drugs (KEPPRA 1000mg UCB Pharma, Belgium) in Iranian healthy volunteers.

Design
Single dose, randomized, two sequences, two period, crossover with a washout period

Settings and conduct
This project will designed as fasting condition in two separated 24 hour time with a week washout time. Each sequences will receive the test or drugs in the first period and crossed over in the second time. The washout time will be determined based on the biological half life of the drug. Sampling process will be perform under supervision of a general physition. The blood will collected in the special blood tubes and plasma were separated by centrifuge and will analyze by HPLC.

Participants/Inclusion and exclusion criteria
24 participants will be selected from non-smoking, not-pregnant people with no history of heart, kidney, and liver disease or disfunctions with both sex (male and female). The ages and BMIs of participant should be in the range of 18-60 and18-25 respectively.

Intervention groups
.Both groups received in cross-over design medication and testing at two different cross-sections and Therefore, the test results are independent of individual differences and it will only show the difference in the formulation of the two drugs.

Main outcome variables
Cmax, Tmax, T1/2, Ke (Elemination)

General information

Reason for update

Acronym

IRCT registration information
IRCT registration number: **IRCT20200105046010N1**
Registration date: **2020-04-12, 1399/01/24**
Registration timing: **registered_while_recruiting**

Last update: **2020-04-12, 1399/01/24**
Update count: **0**

Registration date
2020-04-12, 1399/01/24

Registrant information

Name
Javad Shokri

Name of organization / entity

Country
Iran (Islamic Republic of)

Phone
+98 41 3661 4125

Email address
shokri.j@gmail.com

Recruitment status
Recruitment complete

Funding source

Expected recruitment start date
2020-02-19, 1398/11/30

Expected recruitment end date
2020-07-21, 1399/04/31

Actual recruitment start date
empty

Actual recruitment end date
empty

Trial completion date
empty

Scientific title
In- Vivo Bioequivalence study of Levetiracetam tablet 1000mg Cobel Darou (LEVEBEL 1000mg) with brand

drugs (KEPPRA 1000mg UCB Pharma, Belgium) in Iranian healthy volunteers

Public title
Levetiracetam tablet 1000mg (LEVEBEL 1000mg, Cobel Darou) In- Vivo Bioequivalence study in Iranian healthy volunteers
Purpose
Treatment
Inclusion/Exclusion criteria
Inclusion criteria:
General health (liver & heart & kidney) Body mass index (18-25) Informed consent Age (18-60)
Exclusion criteria:
Smoking A history of cardiovascular disease A history of Liver & Kidney disease Pregnancy Alcohol & Drug addiction Hypersensitivity
Age
From **18 years** old to **55 years** old
Gender
Both

Phase
Bioequivalence
Groups that have been masked

- Participant

Sample size
Target sample size: **24**
Randomization (investigator's opinion)
Randomized
Randomization description
Individuals are randomly selected with advertising 24 volunteers categorized in two sequences randomly.the type of drug (Sample and Brand drug) will prescribe with lottery.
Blinding (investigator's opinion)
Single blinded
Blinding description
Candidates are not aware of the test drug or brand name.
Placebo
Not used
Assignment
Crossover
Other design features
Two periode / Two sequence with a washout time

Secondary Ids

empty

Ethics committees

1

Ethics committee
Name of ethics committee
Tabriz University of Medical Sciences ethics committe
Street address
No. 48, Ferdows street, Ferdowsi Sq.
City
Tabriz
Province
East Azarbaijan
Postal code
5167874434
Approval date
2020-01-20, 1398/10/30
Ethics committee reference number
code: IR. TBZMED.REC.1398.1165

Health conditions studied

1

Description of health condition studied
in this study the bioequivalence of test and brand of levetiracetam will evaluated.
ICD-10 code
ICD-10 code description

Primary outcomes

1

Description
Drug analysis in plasma or whole blood
Timepoint
After blood sampling
Method of measurement
HPLC, LC-MS/MS or UPLC-MS/MS

Secondary outcomes

empty

Intervention groups

1

Description
Crossover study with two intervention groups. Intervention group A (Sequence 1, volunteers 1-12) and intervention group B (sequence 2, volunteers 13-24) without control group based on the guidelines of FDA for bioequivalence study. intervention parameters including: type & dose of the drug, type of dosage form, sampling intervals,sample preparation method, feeding or fasting conditions, analytical method and individual differences between subjects. single dose, randomized, double blind, two ways, two periods study.
Category
Other

Recruitment centers

1

Recruitment center
Name of recruitment center
Simin baspar teyf gostar company
Full name of responsible person
Javad Shokri

Street address
No. 48, Ferdos street
City
Tabriz
Province
East Azarbaijan
Postal code
5167874434
Phone
+98 41 3384 2724
Fax
+98 41 3384 2724
Email
shokri.j@gmail.com

Sponsors / Funding sources

1

Sponsor
Name of organization / entity
Cobel Darou Pharmaceutical Company
Full name of responsible person
Dr Sarfarzi R&D manager
Street address
Tehran, Argantin Sq, Alvand street, Corner of Cambys Alley
City
Tehran
Province
Tehran
Postal code
13897 - 76363
Phone
+98 21 8867 1230
Fax
+98 21 8867 1240
Email
info@cobeldarou.com
Grant name
Grant code / Reference number
Is the source of funding the same sponsor organization/entity?
Yes
Title of funding source
Cobel Darou Pharmaceutical Company
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
Industry

Person responsible for general inquiries

Contact
Name of organization / entity
Tabriz University of Medical Sciences
Full name of responsible person
Javad Shokri
Position
Professor
Latest degree
Ph.D.
Other areas of specialty/work
Medical Pharmacy
Street address
Tabriz University of Medical Sciences, Faculty of Pharmacy
City
Tabriz
Province
East Azarbaijan
Postal code
5166414766
Phone
+98 41 3334 8489
Email
shokri.j@gmail.com

Person responsible for scientific inquiries

Contact
Name of organization / entity
Tabriz University of Medical Sciences
Full name of responsible person
Javad shokri
Position
Professor
Latest degree
Ph.D.
Other areas of specialty/work
Pharmaceutical Sciences
Street address
Tabriz University Faculty of Pharmacy
City
Tabriz
Province
East Azarbaijan
Postal code
5166414766
Phone
+98 41 3334 8489
Email
shokri.j@gmail.com

Person responsible for updating data

Contact
Name of organization / entity
Tabriz University of Medical Sciences
Full name of responsible person
Javad shokri
Position
Professor
Latest degree
Ph.D.
Other areas of specialty/work

Others

Street address

Tabriz University faculty of Pharmacy

City

Tabriz

Province

East Azarbaijan

Postal code

5166414766

Phone

+98 41 3334 8489

Email

shokri.j@gmail.com

Sharing plan

Deidentified Individual Participant Data Set (IPD)

No - There is not a plan to make this available

Justification/reason for indecision/not sharing IPD

These data are as secure between researcher and related industries

Study Protocol

No - There is not a plan to make this available

Statistical Analysis Plan

No - There is not a plan to make this available

Informed Consent Form

Yes - There is a plan to make this available

Clinical Study Report

No - There is not 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

Only protocol and methods of study are sharable

When the data will become available and for how long

After finishing of the protocol(Probably 6 months receiving IRCT code

To whom data/document is available

Pharmaceutical and medical sciences researchers

Under which criteria data/document could be used

Projects information's for any publications is not allowed.

From where data/document is obtainable

contact with E-mail of the main researcher

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

Personal and academic details and the aim of data request.

Comments