

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 be designed as fasting condition in two separated 24 hour time with a week washout time. Each sequence 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 performed under supervision of a general physician. The blood will be collected in the special blood tubes and plasma will be separated by centrifuge and will be analyzed by HPLC.

Participants/Inclusion and exclusion criteria

24 participants will be selected from non-smoking, non-pregnant people with no history of heart, kidney, and liver disease or disfunctions with both sex (male and female). The ages and BMIs of participants should be in the range of 18-60 and 18-25 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

C_{max}, T_{max}, T_{1/2}, K_e (Elimination)

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

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No. 48, Ferdos street
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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

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Person responsible for scientific inquiries

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Person responsible for updating data

Contact

Name of organization / entity

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Full name of responsible person

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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