Clinical Trial Protocol
Iranian Registry of Clinical Trials

18 Sep 2026

Pharmacokinetic assessments of Escitalopram tablet with brand drugs (Cipralex 20mg Loundbeck A/S Denmark).

Protocol summary

Study aim

In- Vivo Bioequivalence study of Escitalopram tablet 20mg ABIDI (Ezipam 20mg) with brand drugs (Cipralex 20mg Loundbeck A/S Denmark).

Design

Single dose of Escitalopram 20 mg Abidi Pharmaceutical Company.

Settings and conduct

This study will be conducted in two-way, cross-over and fasting, and on two sets of healthy volunteers. The study will be conducted in two periods of twenty-four hours.The interval between these two periods, which is called the wash-out time, is determined by the half-life of the drug plasma, which according to scientific sources should be at least 5 to 7 half-life of the drug in the case of the drug under study. The plan will take a week to clean up the drug, given the biological half-life of the drugs in the drug form.In the first round, candidates are divided into two groups, and the first group receives a test tablet and the second group receives a similar tablet. Blood samples will taken by the volunteer by the technician immediately after taking the drug, and the preparation steps of the samples, including plasma separation and drug extraction, are performed to analyze the amount of drug

Participants/Inclusion and exclusion criteria

24 participants will be selected from non-smoking, non-pregnant people without history of heart, kidney and liver disease from both sex (male & female). The ages and BMIs of participant should be in the range of 18-55 and 18-28 respectively.

Intervention groups

Intervention group Single dose Escitalopram tablet 20mg Abidi Pharmaceutical Company and Control group Single dose of Cipralex tablet with brand drugs 20mg Loundbeck A/S.

Main outcome variables

Determination of blood drug concentration.

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20200105046010N14**
Registration date: **2020-11-02, 1399/08/12**
Registration timing: **prospective**

Last update: **2020-11-02, 1399/08/12**
Update count: **0**

Registration date

2020-11-02, 1399/08/12

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

2020-12-24, 1399/10/04

Expected recruitment end date

2021-08-26, 1400/06/04

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Pharmacokinetic assessments of Escitalopram tablet with brand drugs (Cipralex 20mg Loundbeck A/S Denmark).

Public title
In-vivo Bioequivalence Test of Escitalopram tablet with brand drug Cipralex Made by Loundbeck A/S Denmark.
Purpose
Treatment
Inclusion/Exclusion criteria
Inclusion criteria:
General health (liver, heart, kidney) Body mass index(18-28) Informed consent Age(18-60)
Exclusion criteria:
Smoking Pregnancy Alcohol & Drug addiction
Age
From **18 years** old to **60 years** old
Gender
Male

Phase
Bioequivalence
Groups that have been masked

- Participant

Sample size
Target sample size: **24**
Randomization (investigator's opinion)
Randomized
Randomization description
Random allocation law is the simplest method of finite randomization.This method represents a large block for the entire sample size,This means that a balance in the number of people assigned to each group will be achieved at the end of the study.For this purpose, first determine a total sample size (24 people), then write the names of the people on paper, and after folding in aluminum foil, pour it into a glass, and then randomly remove the papers and open the first 12 people in group A and The rest are selected as group B.
Blinding (investigator's opinion)
Single blinded
Blinding description
Candidates are not aware of the test drug or brand name. In a one-blind study, information that could distort the test result is hidden from the candidates, but the person in charge of the test is aware of it.Escitalopram and Escitalopram ® are removed from their packaging by the executor and placed in similar and coded cans. Volunteers will not be informed about receiving the brand or test dosage form.
Placebo
Not used
Assignment
Crossover
Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee
Name of ethics committee
Tabriz University of Medical Sciences Ethics Committee
Street address
Third floor, Central Bulding of Tabriz University of Medical Sciences, Daneshgah St.
City
Tabriz
Province
East Azarbaijan
Postal code
5166614766
Approval date
2019-11-25, 1398/09/04
Ethics committee reference number
IR.TBZMED.REC.1398.912

Health conditions studied

1

Description of health condition studied
In this study, the disease is not examined. Subject bioequivalence test and reference tablets Escitalopram studied.
ICD-10 code
ICD-10 code description

Primary outcomes

1

Description
Determination of blood drug concentration.
Timepoint
Sampling times in this study will be 0, 1, 2, 2:30, 3, 3:20, 3:40, 4, 4:20, 4: 40, 5, 6, 8, 10, 12, 24, 48, 72 hours.
Method of measurement
Liquid Chromatography with tandem mass spectroscopy detector

Secondary outcomes

empty

Intervention groups

1

Description
Intervention group: Single dose Escitalopram tablet 20mg Abidi Pharmaceutical Company.
Category
Treatment - Drugs

2

Description
Control group:Single dose of Cipralex tablet with brand

drugs 20mg Loundbeck A/S Denmark

Category

Treatment - Drugs

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

Email

Shokri.j@gmail.com

Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Abidi Pharmaceutical Company

Full name of responsible person

Amir Razavian

Street address

No. 72, Obaidi Boulevard, Karaj special road, 8 km of Shahid Lashkari highway

City

Tehran

Province

Tehran

Postal code

1389776363

Phone

+98 21 4452 2451

Email

info@abidi-diabetes.com

Grant name

Grant code / Reference number

Is the source of funding the same sponsor organization/entity?

No

Title of funding source

Abidi 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

Other

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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Faculty of Pharmacy, University of Medical Sciences, Daneshgah Street,Tabriz East Azerbayjan

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Person responsible for scientific inquiries

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Professor

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Person responsible for updating data

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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 date 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
No - There is not 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 the request.

Comments