Clinical Trial Protocol
Iranian Registry of Clinical Trials

28 Jun 2026

Comparative bioequivalence study of Escitalopram 20 mg F.C. Tablet of Karen. and Cipralex of Lundbeck Limited as reference in 24 healthy male under fasting.

Protocol summary

Study aim

This study will be performed to compare the pharmacokinetics and invivo parameters of Escitalopram 20 mg F.C. Tablet formulation as a test product with Cipralex 20 mg Tablet formulation as a reference product and to evaluate the bioequivalence of these two formulations.

Design

Non-blinded, randomized, crossover in vivo bioequivalence study in 24 healthy males under fasting conditions. Block randomization for a treatment sequence of Test/Reference or Reference/Test is used.

Settings and conduct

During each study period, volunteers will receive a single dose intervention (1 or 2) in the Farabi Clinic (Eslamshahr, Tehran).17 blood samples were collected during 72 hours post intervention. A 14-day washout interval separated to study periods.

Participants/Inclusion and exclusion criteria

Inclusion Criteria: Healthy subjects (male) between 18 – 40 years of age and Body Mass Index (BMI) between 18.5 and 30 (inclusive), calculated as kg/m2. Sitting blood pressure less than 100/ 60 mm Hg. Exclusion Criteria: Known hypersensitivity or idiosyncratic reaction to Escitalopram or inactive Allergy to any medication, substance, or food. History of cardiovascular, kidney, hepatic, muscular, metabolic, gastrointestinal (including constipation), neurologic, endocrine, any kind of anemia, asthma, and mental disease.

Intervention groups

Intervention group 1: Escitalopram 20 mg F.C. Tablet, produced by Karen. is the test product. In each period, 12 of 24 subjects will be given a single oral dose of this product. Intervention group 2: Cipralex 20 mg Tablet, produced by Lundbeck Limited is the reference product. In each period, 12 of 24 subjects will be given a single oral dose of this product.

Main outcome variables

Peak Plasma Concentration

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20180620040164N44**
Registration date: **2023-04-20, 1402/01/31**
Registration timing: **prospective**

Last update: **2023-04-20, 1402/01/31**
Update count: **0**

Registration date

2023-04-20, 1402/01/31

Registrant information

Name
Behzad Montaha Sangari
Name of organization / entity
Noor research and educational institute (Tavan)
Country
Iran (Islamic Republic of)
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Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2023-05-05, 1402/02/15

Expected recruitment end date

2023-05-20, 1402/02/30

Actual recruitment start date

empty

Actual recruitment end date
empty
Trial completion date
empty

Scientific title
Comparative bioequivalence study of Escitalopram 20 mg F.C. Tablet of Karen. and Cipralex of Lundbeck Limited as reference in 24 healthy male under fasting.

Public title
Comparative in vivo evaluation of 2 Escitalopram 20 mg F.C. Tablet formulations.
Purpose
Treatment
Inclusion/Exclusion criteria
Inclusion criteria:
Healthy subjects (male) between 18 – 40 years of age and Body Mass Index (BMI) between 18.5 and 30 (inclusive), calculated as kg/m2. Sitting blood pressure less than 100/ 60 mm Hg; Subjects with no significant diseases or clinically significant abnormal findings during screening, medical history, clinical examination and laboratory evaluations. Subjects with normal ECG and vital signs. Subjects who agree with patient consent form.
Exclusion criteria:
Known hypersensitivity or idiosyncratic reaction to Escitalopram or inactive Allergy to any medication, substance, or food. History of cardiovascular, kidney, hepatic, muscular, metabolic, gastrointestinal (including constipation), neurologic, endocrine, any kind of anemia, asthma, and mental disease. Muscular trauma 21 days before the beginning of the study. Administration of any medication in the 14 days or 5 half-lives (whatever longer) previous to the beginning of the study and might need drug intake during study period. Use of any medication known to alter hepatic enzyme activity within 28 days prior to the initial dose of study medication. Subjects who have a history of alcohol or substance abuse within the last 5 years. Heavy drinker of alcohol, grapefruit juice or caffeinated drinks or who are on special diet (such as vegetarians) or do exertional physical activity. A history of difficulty with donating blood or donation of more than 450 ml blood within 60 days prior to the start of the study.
Age
From **18 years** old to **40 years** old
Gender
Male

Phase
Bioequivalence
Groups that have been masked
No information
Sample size
Target sample size: **24**
Randomization (investigator's opinion)
Randomized
Randomization description
The randomization schedule will be generated with https://www.sealedenvelope.com/simple-randomiser/v1/lists. A 2*2 block randomization list is created. We have 12 blocks and within each two volunteer numbers (allocated after screening) for all 24 volunteers. According to this list, a treatment sequence of Test/Reference or Reference/Test will be given to each volunteer.
Blinding (investigator's opinion)
Not blinded
Blinding description
Placebo
Not used
Assignment
Crossover
Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee
Name of ethics committee
Ethics Committee,School of Pharmacy,Nursing&Midwifery-Shahid Beheshti University of medical sciences
Street address
Niayesh Highway, Valiasr Ave, Tehran, Iran
City
Tehran
Province
Tehran
Postal code
1996835113
Approval date
2023-03-07, 1401/12/16
Ethics committee reference number
IR.SBMU.PHARMACY.REC.1401.290

Health conditions studied

1

Description of health condition studied
Mood disorder due to known physiological condition with major depressive-like episode
ICD-10 code
F06.32
ICD-10 code description
Mood disorder due to known physiological condition with major depressive-like episode

Primary outcomes

1

Description
Peak Plasma Concentration (Cmax)
Timepoint
17 blood samples will be withdrawn pre-dose and at 1, 2, 2/5, 3, 3/5, 4, 4/5, 5, 5/5, 6, 8, 10, 12, 24, 48 and 72

hours after intervention.

Method of measurement

Using non-compartmental model of Win-Nonlin Professional software version 3.2.A (Pharsight Corporation, USA)

Secondary outcomes

1

Description

AUC (Area Under the Concentration-Time Curve)

Timepoint

17 blood samples will be withdrawn pre-dose and at 1, 2, 2.5, 3, 3.5, 4, 4.5, 5, 5.5, 6, 8, 10, 12, 24, 48 and 72 hours after intervention.

Method of measurement

Using non-compartmental model of Win-Nonlin Professional software version 3.2.A (Pharsight Corporation, USA)

Intervention groups

1

Description

Intervention group 1:Escitalopram 20 mg F.C. Tablet , produced by Karen. is the test product. In each period, 12 of 24 subjects will be given single oral dose of this product. After 14-day wash-out period the intervention 2 will be given to these subjects.

Category

Treatment - Drugs

2

Description

Intervention group 2: Cipralex 20 mg tablet, produced by Boehringer is the reference product. In each period, 12 of 24 subjects will be given single oral dose of this product. After 14-day wash-out period the intervention 1 will be given to these subjects.

Category

Treatment - Drugs

Recruitment centers

1

Recruitment center

Name of recruitment center

Hakim Farabi Clinic

Full name of responsible person

Ebrahim Siahpoosh

Street address

No. 57, Shemshad alley, in front of Sallor town

City

Tehran

Province

Tehran

Postal code

4635314588

Phone

+98 21 9253 5647

Email

partochem@gmail.com

Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Karen Pharma and Food Supplement Co.

Full name of responsible person

Zahra Mortazavi

Street address

No: 3, Western Nahid st. Africa Blvd.

City

Tehran

Province

Tehran

Postal code

۱۴۵۹۹۶۵۲۰۴

Phone

+98 21 2620 4283

Email

info@karenpharma.com

Grant name

Grant code / Reference number

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

Yes

Title of funding source

Karen Pharma and Food Supplement Co.

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

Noor Research & Development Institute

Full name of responsible person

Ali aghaei

Position

Master

Latest degree

Master

Other areas of specialty/work

Pharmacy

Street address

Sharif innovation station, North Habibollah Street, Hosseini Square, Teymoury Street, Tarasht.

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Person responsible for scientific inquiries

Contact
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Tavan Institute
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Other areas of specialty/work
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Phone
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mforoutan@gmail.com

Person responsible for updating data

Contact
Name of organization / entity
Tavan Institute
Full name of responsible person
Ali Aghaei
Position
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Master
Other areas of specialty/work
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City
Tehran
Province
Tehran
Postal code
1459926609
Phone
+98 21 6600 4027
Email
partochem@gmail.com

Sharing plan

Deidentified Individual Participant Data Set (IPD)
Undecided - It is not yet known if there will be a plan to make this available
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
No - There is not a plan to make this available