Clinical Trial Protocol
Iranian Registry of Clinical Trials

09 Jun 2026

Randomized, single-dose, crossover comparative bioequivalence study of Escitalopram 10 mg film-coated tablets of Actoverco. and Lundbeck Limited Co. in 18 healthy male under fasting conditions

Protocol summary

Study aim

This study was performed to compare the pharmacokinetics and invivo parameters of 10 mg Escitalopram tablet formulation as a test product with Cipralex® 10 mg tablet formulation as a reference product and to evaluate the biocompatibility of these two formulations.

Design

Randomized, single-dose, crossover comparative bioequivalence study of Escitalopram 10 mg F.C. tablets of Actoverco and Lundbeck Limited Co. in 18 healthy male under fasting conditions.

Settings and conduct

In each period, volunteers will receive a single dose of the treatment in the Farabi Clinic (Eslamshahr, Tehran). 2 dosing periods were separated by a 14-day washout period.

Participants/Inclusion and exclusion criteria

Healthy subjects (male) between 18 – 45 years of age and Body Mass Index (BMI) between 18.5-30 (inclusive), calculated as kg/m2. Subjects with no significant diseases or clinically significant abnormal findings during screening, medical history, clinical examination and laboratory evaluations. Known hypersensitivity to Escitalopram or inactive ingredients. Acute and chronic cardiovascular, respiratory, gastrointestinal diseases, neuroendocrine disorders, blood system disorders and renal or hepatic impairment. Subjects who have a history of alcohol or substance abuse within the last 5 years. Muscular trauma 21 days before the beginning of the study. Subjects who have a history of alcohol or substance abuse within the last 5 years.

Intervention groups

Intervention group: Intervention group (test): Escitalopram 10 mg tablet, produced by Actoverco. is the test product. In each period, 9 of 18 subjects will be given single oral dose of this product. Intervention group (Reference): Escitalopram 10 mg tablet, produced by Lundbeck Limited is the reference product. In each period, 9 of 18 subjects will be given single oral dose of this product.

Main outcome variables

Peak Plasma Concentration

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20180620040164N5**
Registration date: **2021-01-05, 1399/10/16**
Registration timing: **retrospective**

Last update: **2021-01-05, 1399/10/16**
Update count: **0**

Registration date

2021-01-05, 1399/10/16

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

2019-11-30, 1398/09/09

Expected recruitment end date
2019-12-25, 1398/10/04
Actual recruitment start date
2019-11-30, 1398/09/09
Actual recruitment end date
2019-12-25, 1398/10/04
Trial completion date
2020-09-19, 1399/06/29

Scientific title
Randomized, single-dose, crossover comparative bioequivalence study of Escitalopram 10 mg film-coated tablets of Actoverco. and Lundbeck Limited Co. in 18 healthy male under fasting conditions

Public title
bioequivalence study of Escitalopram 10 mg film-coated tablets in 18 healthy male under fasting conditions
Purpose
Treatment
Inclusion/Exclusion criteria
Inclusion criteria:
Healthy subjects (male) between 18 – 45 years of age and Body Mass Index (BMI) between 18.5-30 (inclusive), calculated as kg/m2. 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. Subjects who have a history of alcohol or substance abuse within the last 5 years
Age
From **18 years** old to **45 years** old
Gender
Male

Phase
Bioequivalence
Groups that have been masked
No information
Sample size
Target sample size: **18**
More than 1 sample in each individual
Number of samples in each individual: **36**
In each period, 18 blood samples are collected from each subject and this study includes 2 periods
Actual sample size reached: **18**
More than 1 sample in each individual
Actual sample size in each individual: **36**
In each period, 18 blood samples are collected from each subject and this study includes 2 periods
Randomization (investigator's opinion)
Randomized
Randomization description
The randomization schedule is generated with the BEAR statistical software (Release V2.7.7). Each volunteer is randomly assigned to one of the 2 different sequence of treatments according to their entrance number to study which is allocated after screening.
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 of Shahid Beheshti University of Medical Sciences
Street address
Sharif innovation station, North Habibollah, Hosseini Squ., Teymoury St., Tarasht
City
Tehran
Province
Tehran
Postal code
19839-63113
Approval date
2019-10-07, 1398/07/15
Ethics committee reference number
IR.SBMU.PHARMACY.REC.1398.161

Health conditions studied

1

Description of health condition studied
Bioequivalence investigation of the generic (Actoverco.) Escitalopram 10 mg tablet with brand (Cipralex) Lundbeck Limited 10 mg tablet.
ICD-10 code
ICD-10 code description

Primary outcomes

1

Description
Peak Plasma Concentration (Cmax)
Timepoint
During 2 months 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
During 2 months 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: (test): Escitalipram 10 mg tablet, produced by Actoverco. is the test product. In each period, 9 of 18 subjects will be given single oral dose of this product.
Category
Treatment - Drugs

2

Description
Control group: (reference): Cipralex® 10 mg tablet, produced by Lundbeck Limited co. is the reference product. In each period, 9 of 18 subjects will be given single oral dose of this product.
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, Sallor city
City
Eslamshahr
Province
Tehran
Postal code
4635314588
Phone
+98 21 9253 5647
Email
mina.hasanabadi@yahoo.com

Sponsors / Funding sources

1

Sponsor
Name of organization / entity
Actover pharmaceutical co.
Full name of responsible person
Nahaleh Naraghi
Street address
58 plaque, 8th St., Gisha
City
Tehran
Province
Tehran
Postal code
1446863914
Phone
+98 21 4162 7000
Email
info@actoverco.com
Grant name
Grant code / Reference number
Is the source of funding the same sponsor organization/entity?
Yes
Title of funding source
Actover pharmaceutical 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
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Person responsible for updating data

Contact
Name of organization / entity
Tavan Institute
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Position
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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
It's not specified yet
Study Protocol
Undecided - It is not yet known if there will be 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