

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 Ciprallex® 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)

Phone

+98 21 6600 7026

Email address

info@tavaninstitute.ir

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 (C_{max})

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

Pharmacy

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Person responsible for scientific inquiries

Contact

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Seyed Mohsen Foroutan
Position
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Medical Pharmacy
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Person responsible for updating data

Contact

Name of organization / entity
Tavan Institute
Full name of responsible person

Ali Aghaei
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