Clinical Trial Protocol
Iranian Registry of Clinical Trials

09 Jun 2026

Comparative bioequivalence study of Duloxetine 30 mg enteric coated capsule of ACTOVERCO and Eli Lilly Inc. in 24 healthy male under fasting conditions

Protocol summary

Study aim

This study will be performed to compare the pharmacokinetics and invivo parameters of Duloxetine 30 mg enteric coated capsule formulation as a test product with Cymbalta® tablet formulation as a reference product and to evaluate the biocompatibility of these two formulations.

Design

Randomized, single-dose, crossover comparative bioequivalence study of Duloxetine 30 mg enteric coated capsule of Actover. and Eli Lilly. in 24 healthy male under fasting.

Settings and conduct

In each period, volunteers will receive a single dose of the treatment in the Farabi Clinic (Eslamshahr, Tehran). 2 dosing periods will be separated by a 7-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 and 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 or idiosyncratic reaction to Duloxetine or inactive ingredients. History of sensitivity to heparin or heparin induced thrombocytopenia. Clinically significant infections within the past 3 months, evidence of any infection within the past 7 days, history of disseminated herpes simplex infection or recurrent (>1 episode) or disseminated herpes zoster. Vaccination with live or attenuated vaccines within 6 weeks prior to dosing.

Intervention groups

Intervention group (test):Duloxetine 30 mg enteric coated capsule, produced by Actover is the test product. In each period, 12 of 24 subjects will be given a single oral dose of this product. Intervention group (Reference): Cymbalta® capsule, produced by Eli Lilly 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: **IRCT20180620040164N23**
Registration date: **2022-04-03, 1401/01/14**
Registration timing: **retrospective**

Last update: **2022-04-03, 1401/01/14**
Update count: **0**

Registration date

2022-04-03, 1401/01/14

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

2021-06-18, 1400/03/28

Expected recruitment end date

2021-06-25, 1400/04/04

Actual recruitment start date
empty

Actual recruitment end date
empty

Trial completion date
empty

Scientific title
Comparative bioequivalence study of Duloxetine 30 mg enteric coated capsule of ACTOVERCO and Eli Lilly Inc. in 24 healthy male under fasting conditions

Public title
Bioequivalence study of Duloxetine 30 mg enteric coated capsule in 24 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 and 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 who agree with patient consent form.

Exclusion criteria:
Known hypersensitivity or idiosyncratic reaction to Duloxetine or inactive ingredients. History of sensitivity to heparin or heparin induced thrombocytopenia. Clinically significant infections within the past 3 months, evidence of any infection within the past 7 days, history of disseminated herpes simplex infection or recurrent (>1 episode) or disseminated herpes zoster. Vaccination with live or attenuated vaccines within 6 weeks prior to dosing. History of narrow angle glaucoma. Evidence or history of clinically significant hematological, renal, endocrine, pulmonary, gastrointestinal, cardiovascular, hepatic, psychiatric, neurological, or allergic disease Use of prescription or nonprescription drugs and dietary supplements within 14 days or 5 half-lives (whichever is longer) prior to the first dose of investigational product. History of regular alcohol or drug consumption within 6 months before screening Use of any medicinal product that is an inductor or strong inhibitor of CYP450 1A2 or 2D6 (eg, rifampicin, omeprazole, fluvoxamine, ciprofloxacin, fluoxetine, paroxetine, etc) within two weeks before administration of the investigational product and at any time during the study. Use of any medicinal product that inhibits monoamine oxidase A or B (eg, phenelzine, isocarboxacid, linezolid) within two weeks before administration of the investigational product and at any time during the study till at least 5 days after the last dose of investigational product. Consumption of grapefruit or grapefruit juice within 7 days prior to dosing. 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. Fertile male subjects who are unwilling or unable to use a highly effective method of contraception as outlined in this protocol for the duration of the study and for at least 28 days after the last dose of investigational product.

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: **26**

Randomization (investigator's opinion)
Randomized

Randomization description
The randomization schedule will be generated with the BEAR statistical software (Release V2.7.7). Each volunteer will be randomly assigned to one of the 2 different sequence of treatments according to the order of entering the study which will be 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
Niayesh Highway, Valiasr Ave, Tehran, Iran

City
Tehran

Province
Tehran

Postal code
1996835113

Approval date
2020-02-03, 1398/11/14

Ethics committee reference number
IR.SBMU.PHARMACY.REC.1398.265

Health conditions studied

1

Description of health condition studied
Bioequivalence investigation of the generic Actover.Duloxetine 30 mg enteric coated capsule with brand Cymbalta® Eli Lilly capsule.

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: Intervention group: (test): Duloxetine 30 mg enteric coated capsule, produced by Actover is the test product. In each period, 12 of 24 subjects will be given single oral dose of this product.
Category
Treatment - Drugs

2

Description
Intervention group: Intervention group: Duloxetine 30 mg enteric coated capsule, produced by Eli Lilly is the test product. In each period, 12 of 24 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
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4635314588
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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
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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

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Seyed Mohsen Foroutan

Position

Principal investigator

Latest degree

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Person responsible for updating data

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Other areas of specialty/work

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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

t'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