Clinical Trial Protocol
Iranian Registry of Clinical Trials

17 Sep 2026

Bioequivalence Study of Escitalopram 10 mg of Pars Darou and Cipralex manufactured by Lundbeck in 24 Healthy Volunteers

Protocol summary

Study aim

The bioequivalence study of Escitalopram tablet of Alborz Darou company and Ciprolex tablet manufactured by Lundbeck company .

Design

Cross over bioequivalence study

Settings and conduct

Sampling of volunteers is done in Khorazmi Plasma Center in Islamshahr. On the day of sampling, two 10 mg tablets of Escitalopram manufactured by Pars Darou or Lundbeck on two occasions and with a washout period of 14 days, will be administered orally with 240 ml of water to the volunteer. For example, if in the first phase he received the medicine made by Pars Darou company, he will receive the brand medicine two weeks later. In each phase, 5 cc of blood sample will be taken before drug administration and at times 1, 2, 3, 3.5, 4, 4.5, 5, 5.5, 6, 6.5, 7, 8, 10, 24, 48, 72 hours after prescribing the medicine . Two weeks after the start of the study, the volunteer's cooperation in this research ends. The way to cooperate in these three weeks is that the drug is prescribed in the first day and after that 72 hours blood sampling is done at the mentioned times after washout period of two weeks the other drug is administered and blood samples will be taken at the same time

Participants/Inclusion and exclusion criteria

Healthy volunteers , in the age range of 18 to 55 years with a body mass index between 18 and 27 kg per square meter of the body, volunteers who are willing to comply with the requirements of the protocol and provide written informed consent. Non-smokers or smokers who smoke less than 10 cigarettes per day.

Intervention groups

The first group: 12 people who take Alborz Daru tablets
The second group: 12 people who take Lundbeck pills on the same day

Main outcome variables

Plasma concentration and area under the curve of plasma concentration time of test and reference drug

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20220209053979N6**
Registration date: **2023-02-10, 1401/11/21**
Registration timing: **prospective**

Last update: **2023-02-10, 1401/11/21**
Update count: **0**

Registration date

2023-02-10, 1401/11/21

Registrant information

Name
Roya Talari

Name of organization / entity

Country
Iran (Islamic Republic of)

Phone
+98 21 8880 0892

Email address
talari_r@yahoo.com

Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2023-02-20, 1401/12/01

Expected recruitment end date

2023-03-05, 1401/12/14

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Bioequivalence Study of Escitalopram 10 mg of Pars Darou and Cipralex manufactured by Lundbeck in 24 Healthy Volunteers

Public title
Bioeqivalence study of escitalopram 10 mg tablet
Purpose
Other
Inclusion/Exclusion criteria
Inclusion criteria:
Laboratory tests +/- 10% of normal interval Without any history of chronic sickness
Exclusion criteria:
History of medicine consumption Donation of blood sample more than 300 ml within last 30 days
Age
From **18 years** old to **55 years** old
Gender
Both

Phase
Bioequivalence
Groups that have been masked

- Participant
- Data analyser

Sample size
Target sample size: **24**
More than 1 sample in each individual
Number of samples in each individual: **17**
blood samples wil be taken at 1, 2, 3, 3.5, 4, 4.5, 5, 5.5, 6, 6.5, 7, 8, 10, 24, 48, 72 h after drug administration
Randomization (investigator's opinion)
Randomized
Randomization description
Using the rand option of the Excel software, the candidates are divided into two groups, and half of them will receive numbers 1-12 and the test drug, and the other half will receive numbers 13-24 and will receive the reference drug.
Blinding (investigator's opinion)
Double blinded
Blinding description
The tablets of Pars Darou and Lundbeck are both oval shaped and white in color, so the candidate does not know which company's drug he will receive in each phase of the study. On the other hand, the tubes of the volunteers' samples are also coded, so the analyzer does not know which company's drug he is analyzing, so only the researcher and the prescriber know which company's drug is being prescribed.
Placebo
Not used
Assignment
Crossover
Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee
Name of ethics committee
Ethics Committee of Tehran University of Medical Science
Street address
Tehran University of Medical Science, 16 Azar St.,
City
Tehran
Province
Tehran
Postal code
1417713135
Approval date
2023-02-07, 1401/11/18
Ethics committee reference number
IR. TUMS. TIPS. REC. 1401. 108

Health conditions studied

1

Description of health condition studied
A crossover bioequivalence study in 24 healthy volunteers
ICD-10 code
ICD-10 code description

Primary outcomes

1

Description
Plasma concentration time profile, Maximum plasma concentration, AUC
Timepoint
0, 1, 2, 3, 3.5, 4, 4.5, 5, 5.5, 6, 6.5, 7, 8, 10, 12, 24, 48, 72, hours after drug administration
Method of measurement
Liquid chromatography with mass spectrophotometry

Secondary outcomes

1

Description
Plasma concentration and then calculation of pharmacokinetic parameters like Cmax, AUC of test and reference drug.
Timepoint
0, 1, 2, 3, 3.5, 4, 4.5, 5, 5.5, 6, 6.5, 7, 8, 10, 12, 24, 48, 72, hours after drug administration
Method of measurement
Plasma concentration is measured by Liquid chromatography with mass spectrometery and pharmacokientic parameters are calculated by excel.

Intervention groups

1

Description
Intervention group: 1: Oral administration of two tablets of citalopram 10 mg manufactured by Pars Darou Company to 12 healthy volunteers in fasting state with 240 ml of water. Then 17 blood samples are taken from each volunteers at certain time. In the second phase (two weeks later) this process is repeated vice verse. That is, these people will take Lundbeck's medicine and give blood samples at 17 time points

Category
Treatment - Drugs

2

Description
Intervention group: 2: Oral administration of two tablets of citalopram 10 mg manufactured by Lundbeck Company to 12 healthy volunteers in fasting state with 240 ml of water. Then 17 blood samples are taken from each volunteers at certain time. In the second phase (two weeks later) this process is repeated vice verse. That is, these people will take Pars Darou medicine and give blood samples at 17 time points

Category
Treatment - Drugs

Recruitment centers

1

Recruitment center

Name of recruitment center
مرکز پلاسما خوارزمی

Full name of responsible person
Sara Solgi

Street address
No. 13, Shehamat 1st Alley, Ali Ibn Abitalib St., Namaz Square,

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Sponsors / Funding sources

1

Sponsor

Name of organization / entity
Pars Darou Company

Full name of responsible person
Fatemeh Zadsaleh

Street address
No. 13, 144 East St., The first square of Tehran Pars,

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Tehran

Province
Tehran

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1654713691

Phone
+98 21 7770 4061

Email
info@parsdarou.com

Grant name

Grant code / Reference number

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

Title of funding source
Pars Darou 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
Industry

Person responsible for general inquiries

Contact

Name of organization / entity
Kharazmi Plasma Center

Full name of responsible person
Roya Talari

Position
excutor

Latest degree
Ph.D.

Other areas of specialty/work
Medical Pharmacy

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No. 13, Shehamat 1st Alley, Ali Ibn Abitalib St., Namaz Square,

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Person responsible for scientific inquiries

Contact

Name of organization / entity
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Full name of responsible person
Roya Talari

Position
Executer

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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
The bioequivalence study data is completely confidential and according to the contract with Pars Darou Company, it should not be published anywhere.

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