Clinical Trial Protocol
Iranian Registry of Clinical Trials

13 Jun 2026

Single-dose bioequivalence studies of Duloxetine (60 mg) in healthy volunteers

Protocol summary

Study aim
Administration of test (generic) and reference (brand) products to healthy subjects Comparison of bioavailability and pharmacokinetics of two products Evaluation of interchangeability of two products

Design
This clinical trial study with control group was conducted on 26 patients with parallel, double-blind, random allocation, and bio-equivalence phase. 26 healthy volunteers after passing the inclusion and exclusion criteria will be divided into two groups of test and reference. Then, in the second period, the group that received the test drug will receive the reference drug and the other group will receive the test drug.

Settings and conduct
This study was single-dose, randomized, and crossover. In this way, after completing the consent form and being aware of the drug and its side effects, the candidates consume the test product in one period and the reference product in the other period. This study was conducted at Shahid Beheshti School of Pharmacy.

Participants/Inclusion and exclusion criteria
Inclusion criteria: Healthy volunteers aged 18 to 50 years Exclusion criteria: History of liver, kidney and cardiovascular diseases that can affect drug clearance from body History of taking any medication in the last two weeks Creatinine above 2

Intervention groups
Receiving test product Receiving reference product

Main outcome variables
The variables of this study include the maximum plasma concentration of the drug, the time to reach the maximum plasma concentration of the drug and the area below the concentration versus time curve. The first two variables are a measure of drug uptake rate and the third variable is a measure of drug uptake.

General information

Reason for update

Acronym

IRCT registration information
IRCT registration number: **IRCT20210201050197N1**
Registration date: **2021-02-19, 1399/12/01**
Registration timing: **prospective**

Last update: **2021-02-19, 1399/12/01**
Update count: **0**

Registration date
2021-02-19, 1399/12/01

Registrant information

Name
Azadeh Haeri

Name of organization / entity

Country
Iran (Islamic Republic of)

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+98 21 8820 0212

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a_haeri@sbmu.ac.ir

Recruitment status
Recruitment complete

Funding source

Expected recruitment start date
2021-02-26, 1399/12/08

Expected recruitment end date
2021-03-10, 1399/12/20

Actual recruitment start date
empty

Actual recruitment end date
empty

Trial completion date
empty

Scientific title

Single-dose bioequivalence studies of Duloxetine (60 mg) in healthy volunteers

Public title
Bioequivalence of Duloxetine
Purpose
Other
Inclusion/Exclusion criteria
Inclusion criteria:
Healthy volunteer Age: 18-50 year
Exclusion criteria:
History of liver, kidney and cardiovascular diseases that can affect drug clearance from body History of taking any medication in the last two weeks Creatinine above 2
Age
From **18 years** old to **50 years** old
Gender
Both

Phase
Bioequivalence
Groups that have been masked

- Participant
- Care provider

Sample size
Target sample size: **26**
Randomization (investigator's opinion)
Randomized
Randomization description
In order to randomize, in this study, a random allocation rule has been used. For this purpose, first, a total sample size of volunteers who met the inclusion criteria was determined. In this way, 26 people who had passed the entry and exit criteria were selected and then assigned to each number by Excel program, and randomly 13 for the control group and 13 for the experimental group were selected. Then, by matching the number of people with their names, the two groups will be identified. Then, in the second period, the group that received the test drug received the reference drug and the other group received the test drug.
Blinding (investigator's opinion)
Double blinded
Blinding description
Candidates receive medication twice. Once Iranian product (generic) and once the foreign product (reference). Volunteers and study physicians are not aware of what products they have received at every turn. Because the medicine is taken out of its box and blister and given to the volunteers, they will have no knowledge of the type of medicine. The new drug is made in terms of color, smell, taste, consistency, and all appearance characteristics similar to the reference drug so that the participants are blind in this regard.
Placebo
Not used
Assignment
Crossover
Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee
Name of ethics committee
School of Pharmacy Nursing and Midwifery, Shahid Beheshti Medical University
Street address
No 2660, School of Pharmacy Nursing and Midwifery, Shahid Beheshti Medical University, Niayesh building, Valiasr Ave
City
Tehran
Province
Tehran
Postal code
1996835113
Approval date
2021-02-14, 1399/11/26
Ethics committee reference number
IR.SBMU.PHARMACY.REC.1399.342

Health conditions studied

1

Description of health condition studied
Healthy subjects
ICD-10 code
ICD-10 code description

Primary outcomes

1

Description
Plasma drug concentration
Timepoint
1، 2، 3، 4، 5، 5.5، 6، 6.5، 7، 8، 10، 12، 24، 32، 48 hours
Method of measurement
High performance liquid chromatography (HPLC) method

Secondary outcomes

empty

Intervention groups

1

Description
Intervention group: Receiving Iranian medicine (generic product): In this group, each volunteer receives a 60 mg Duloxetine tablets made by Aria Company during a treatment period. After that, blood samples are taken from the volunteers for 24 hours. Blood samples (5 cc) are taken from volunteers at different times (14 times).

This completes a course of study. Pharmacokinetic parameters are calculated and compared by determining the drug concentration in blood samples by High-performance liquid chromatography (HPLC).

Category

Treatment - Drugs

2

Description

Control group: Control group: Receiving reference medicine: In this group, each volunteer receives one reference tablet of 60 mg Duloxetine in a course of treatment. After that, blood samples are taken from the volunteers for 24 hours. Blood samples (5 cc) are taken from volunteers at different times (14 times). This completes a course of study. Pharmacokinetic parameters are calculated and compared by determining the drug concentration in blood samples by High-performance liquid chromatography (HPLC).

Category

Treatment - Drugs

Recruitment centers

1

Recruitment center

Name of recruitment center

School of Pharmacy, Shahid Beheshti University of Medical Sciences

Full name of responsible person

Azadeh Haeri

Street address

No 2660, School of Pharmacy Nursing and Midwifery, Shahid Beheshti Medical University, Niayesh building, Valiasr Ave

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a_haeri@sbmu.ac.ir

Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Arya Pharmaceutical Company

Full name of responsible person

Rahim Shabestari

Street address

Tehran Karaj Highway, Kilometer 17

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Tehran

Province

Tehran

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1397133111

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Email

info@aryapharm.com

Grant name

Grant code / Reference number

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

Yes

Title of funding source

Arya Pharmaceutical 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

Shahid Beheshti University of Medical Sciences

Full name of responsible person

Azadeh Haeri

Position

Assistant professor

Latest degree

Ph.D.

Other areas of specialty/work

Medical Pharmacy

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Person responsible for scientific inquiries

Contact

Name of organization / entity

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Position
Assistant professor
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Person responsible for updating data

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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
Undecided - It is not yet known if there will be a plan to make this available
Statistical Analysis Plan
Undecided - It is not yet known if there will be 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