Clinical Trial Protocol
Iranian Registry of Clinical Trials

17 Sep 2026

A randomized, open label, two treatments, single dose, crossover, bioequivalence study of Dapoxetine 30mg tablet of Alborz Darou Pharm Co., IRAN in comparison of Priligy 30mg tablet of Menarini in 24 healthy adult subjects under fasting condition

Protocol summary

Study aim

A randomized, crossover bioequivalence study of single dose of test formulation (two tablets of Dapoxeyine 30mg produced by Alborz Darou Pharm. Co.) in comparison of reference product (two tablets of Priligy 30mg) by means of AUC0-t and Cmax in healthy, adult human subjects under fasting conditions.

Design

A randomized, open label, single dose, crossover, bioequivalence study in 24 healthy subjects under fasting condition with wash out period of at least one week

Settings and conduct

This study is carried out in Core Research Center of Zahedan University of Medical Sciences located in Imam Ali Hospital in Zahedan. There is a separate space for sampling and forecasting emergency situations in order to accommodate and rest the volunteers. This crossover and open label study was performed on 24 healthy volunteers with wash out period of at least one week. The volunteers' health is verified by the project physician prior to entry into the study, and the volunteers' status is regularly monitored by the project physician on the day of drug administration. This study will be covered by insurance in order to compensate for any adverse effects.

Participants/Inclusion and exclusion criteria

Main Inclusion criteria: Healthy subjects aged between 18 -50 years old and weighted between 50 – 100 kg\\ Main exclusion criteria: Donation a unit of blood or participated in another clinical trial within the last three months; History of drug or alcohol abuse; Used any medication within 7- 14 days before the first treatment;

Intervention groups

Intervention: Single dose of two Dapoxetine 30mg tablets of Alborz darou Pharm Co., IRAN Control: Single dose of two Priligy 30mg tablets of Menarini

Main outcome variables

Plasma concentration of dapoxetine

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20190706044111N18**
Registration date: **2020-05-21, 1399/03/01**
Registration timing: **prospective**

Last update: **2020-05-21, 1399/03/01**
Update count: **0**

Registration date

2020-05-21, 1399/03/01

Registrant information

Name
Ladan Tayebi

Name of organization / entity
Pars Biopharmacy Research Co.

Country
Iran (Islamic Republic of)

Phone
+98 21 8895 6061

Email address
l.tayebi@parsbiopharmacy.com

Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2020-06-21, 1399/04/01

Expected recruitment end date

2021-03-19, 1399/12/29

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

A randomized, open label, two treatments, single dose, crossover, bioequivalence study of Dapoxetine 30mg tablet of Alborz Darou Pharm Co., IRAN in comparison of Priligy 30mg tablet of Menarini in 24 healthy adult subjects under fasting condition

Public title

Bioequivalence study of Dapoxetine 30mg tablet of Alborz Darou Pharm Co., IRAN

Purpose

Other

Inclusion/Exclusion criteria

Inclusion criteria:

- Aged between 18 - 50 years - Body weight between 50 – 100 kg - Having good health on the basis of medical history and physical & clinical examination - Understand the procedures and give written informed consent

Exclusion criteria:

Subject had undergone surgery of the gastro-intestinal tract Subject had donated a unit of blood or participated in another clinical trial, within the last two months before the first treatment. Subject had a history of drug or alcohol abuse. Subject who smokes more than 10 cigarettes per day. Subject had used any prescription medication within 14 days, or any non-prescription medication within 7 days, before the first treatment.

Age

From **18 years** old to **50 years** old

Gender

Both

Phase

Bioequivalence

Groups that have been masked

No information

Sample size

Target sample size: **24**

More than 1 sample in each individual

Number of samples in each individual: **2**

Each volunteer, 2 times take medicine in the study. One-time test product and the other time reference product with at least one week wash-out period.

Randomization (investigator's opinion)

Randomized

Randomization description

Using Excel software, each subject will be randomly assigned to one of the two sequence AB or BA in a balanced manner.

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 Zahedan University of medical Sciences

Street address

Dr. Hessabi square Zahedan University of Medical Sciences

City

Zahedan

Province

Sistan-va-Balouchestan

Postal code

9816743463

Approval date

2020-04-26, 1399/02/07

Ethics committee reference number

IR.ZAUMS.REC.1399.040

Health conditions studied

1

Description of health condition studied

Premature ejaculation

ICD-10 code

F52.4

ICD-10 code description

Premature ejaculation

Primary outcomes

1

Description

Plasma concentration of dapoxetine

Timepoint

At 0 (before dosing), 0.5, 1.0, 1.5, 2.0, 2.5, 3.0, 4.0, 6.0, 8.0, 10.0, 24.0 & 48.0 hr. after drug administration

Method of measurement

High Performance Liquid Chromatography (HPLC)

Secondary outcomes

empty

Intervention groups

1

Description

Intervention group: Single dose of two Dapoxetine 30mg

tablets of Alborz Darou Pharm Co., IRAN

Category

Other

2

Description

Control group: Single dose of two Priligy 30mg tablets of Menarini

Category

Other

Recruitment centers

1

Recruitment center

Name of recruitment center

Core Research Lab. of ZAUMS

Full name of responsible person

Gholamreza Komeili

Street address

Emam Ali Hospital, Salamat Blv., Khalij-e-Fars Highway

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Zahedan

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Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Alborzdarou Pharm. Co.

Full name of responsible person

Ali Mortazavi

Street address

8th Hekmat street, Alborz Industrial City, Ghazvin

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Province

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Email

info@alborzdarouco.com

Web page address

http://www.alborzdarouco.com

Grant name

Grant code / Reference number

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

Yes

Title of funding source

Alborzdarou Pharm. 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

Pars Biopharmacy Research Co.

Full name of responsible person

Ladan Tayebi

Position

Managing Director

Latest degree

Medical doctor

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

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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

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

Clinical Study Report

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

Analytic Code

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

Data Dictionary

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