Clinical Trial Protocol
Iranian Registry of Clinical Trials

08 Jul 2026

Comparative bioequivalence study of Sertraline 100 mg F.C. Tablet of Dorsa Pharmaceutical Co. and PFIZER Inc. in 24 healthy male under fasting

Protocol summary

Study aim

This study will be performed to compare the pharmacokinetics and invivo parameters of Sertraline 100 mg F.C. tablet formulation as a test product with Zoloft® tablet formulation as a reference product and to evaluate the biocompatibility of these two formulations.

Design

Randomized, single-dose, crossover comparative bioequivalence study of Gabapentin 300 mg of Dorsa Pharmaceutical Co. and PFIZER 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 20 – 45 years of age and Body Mass Index (BMI) within 15% of normal range according to the accepted normal values 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 with normal vital signs. Subjects with known allergy to the products tested. History or presence of significant easy bruising or bleeding; Systolic blood pressure less than 100 mm Hg or more than 140 mm Hg.

Intervention groups

Intervention group (test):Sertraline 100 mg F.C. Tablet, produced by Dorsa Pharmaceutical Co. is the test product. In each period, 12 of 24 subjects will be given a single oral dose of this product. Intervention group (Reference): Zoloft® Tablet, produced by PFIZER 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: **IRCT20180620040164N21**
Registration date: **2022-02-20, 1400/12/01**
Registration timing: **prospective**

Last update: **2022-02-20, 1400/12/01**
Update count: **0**

Registration date

2022-02-20, 1400/12/01

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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info@tavaninstitute.ir

Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2022-02-25, 1400/12/06

Expected recruitment end date

2022-03-11, 1400/12/20

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Comparative bioequivalence study of Sertraline 100 mg F.C. Tablet of Dorsa Pharmaceutical Co. and PFIZER Inc. in 24 healthy male under fasting

Public title

Bioequivalence study of Sertraline 100 mg F.C. Tablet in 24 healthy male under fasting conditions

Purpose

Treatment

Inclusion/Exclusion criteria

Inclusion criteria:

Healthy subjects (male) between 20 – 45 years of age and Body Mass Index (BMI) within 15% of normal range according to the accepted normal values 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 with normal vital signs. Subjects who agree with patient consent form.

Exclusion criteria:

Subjects with known allergy to the products tested. History or presence of significant easy bruising or bleeding. Systolic blood pressure less than 100 mm Hg or more than 140 mm Hg. Diastolic blood pressure less than 60 mm Hg or more than 90 mm Hg. Pulse rate less than 50/minute or more than 100/minute. Smoking more than 10 cigarettes per day and could not tolerate cigarette cessation during each clinical period. Subjects who has used any drug including prescription or Over-The-Counter (OTC) drugs within 14 days prior to the start of the study and might need drug intake during study period. History of alcohol or drug abuse within 2 years before the start of the study. Heavy drinker of caffeine, grapefruit juice or caffeinated drinks or who are on special diet (such as vegetarians) or do exertional physical activity. A history of difficulty with donating blood or donation of more than 500 ml blood within 7 days prior to the start of the study.

Age

From **20 years** old to **45 years** old

Gender

Male

Phase

Bioequivalence

Groups that have been masked

No information

Sample size

Target sample size: **24**

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

2021-08-10, 1400/05/19

Ethics committee reference number

IR.SBMU.PHARMACY.REC.1400.115

Health conditions studied

1

Description of health condition studied

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: (test):Sertraline 100 mg F.C. Tablet, produced by Dorsa Pharmaceutical Co. 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: Sertraline 100 mg F.C. Tablet, produced by PFIZER is the refrence 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

City

Tehran

Province

Tehran

Postal code

4635314588

Phone

+98 21 9253 5647

Email

mina.hasanabadi@yahoo.com

Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Dorsa Pharmaceutical Co.

Full name of responsible person

Amir esmael Saghafinia

Street address

Teimori-Shahid Salehi Blv-Fanavari Tarash Tower-8th floor

City

Tehran

Province

Tehran

Postal code

۱۴۵۹۹۶۵۲۰۴

Phone

+98 21 5461 2000

Email

info@dorsadarou.com

Grant name

Grant code / Reference number

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

Yes

Title of funding source

Dorsa 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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Sharif innovation station, North Habibollah, Hosseini Squ., Teymoury St., Tarasht

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Person responsible for scientific inquiries

Contact

Name of organization / entity
Tavan Institute
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Seyed Mohsen Foroutan
Position
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Latest degree
Ph.D.
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Medical Pharmacy
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Email
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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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Latest degree
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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