Clinical Trial Protocol
Iranian Registry of Clinical Trials

17 Sep 2026

A study to compare the relative bioavailability of Sobhandarou and Pfizer formulations of sertraline 50 and 100 mg tablets in 24 healthy adult male volunteers under fasting conditions

Protocol summary

Summary

This randomized, single-dose, three-way, crossover study is conducted to compare the relative bioavailability of three formulations of sertraline hydrochloride tablets under fasting conditions in 24 healthy adults male volunteers. In each study period, a single 100 mg dose is administered to the subjects following an overnight fast of at least 10 hours. The test formulations are sertraline hydrochloride 50 and 100 mg tablets manufactured by Sobhandarou and the reference formulation is ZOLOFT® (sertraline hydrochloride) 100 mg tablet manufactured by Pfizer. The subjects will receive the test products and the reference product in three periods; the order of administration will be according to the dosing randomization schedule. There will be a 7-day interval between treatments. Venous blood (3 ml) for the determination of sertraline in plasma is sampled before dosing and at 1, 2, 3, 4, 5, 6, 7, 8, 10, 12, 24, 48, and 72 hours after dosing (a total of 14 samples per profile). Criteria for the evaluation include the time course of the plasma concentrations of sertraline over the 72 h after the administration of the products as summarized by the area under the curve from time zero to infinity (AUC0-inf), the maximum plasma concentration (Cmax), time to reach Cmax (Tmax) and plasma half-life (t1/2). Statistical analysis is performed to evaluate the relative bioavailability of the test formulations to that of the reference product.

General information

Acronym

IRCT registration information

IRCT registration number: **IRCT2016022813776N3**
Registration date: **2016-12-27, 1395/10/07**
Registration timing: **registered_while_recruiting**
Last update:
Update count: **0**

Registration date

2016-12-27, 1395/10/07

Registrant information

Name

Hossein Amini

Name of organization / entity

Golestan University of Medical Sciences

Country

Iran (Islamic Republic of)

Phone

+98 17 1442 1651

Email address

hamini@sbmu.ac.ir

Recruitment status

Recruitment complete

Funding source

Sobhandarou Pharmaceutical Company

Expected recruitment start date

2016-11-25, 1395/09/05

Expected recruitment end date

2017-02-08, 1395/11/20

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

A study to compare the relative bioavailability of Sobhandarou and Pfizer formulations of sertraline 50 and 100 mg tablets in 24 healthy adult male volunteers under fasting conditions

Public title

Bioequivalence study of sertraline hydrochloride 50 and 100 mg tablets under fasting conditions

Purpose

Health service research

Inclusion/Exclusion criteria

Inclusion criteria: 1. Males, 18-50 years of age (inclusive). 2. The subject is able and willing to provide written informed consent. 3. The subject is available for the entire study period and is willing to adhere to protocol requirements as evidenced by written informed consent. 4. The subject has stable residence and telephone. 5. Good health as determined by lack of clinically significant abnormalities in health assessments performed at screening. Exclusion criteria: 1. History of allergy or sensitivity to sertraline hydrochloride or other selective serotonin reuptake inhibitor's (SSRI's), or history of any drug hypersensitivity or intolerance which, in the opinion of the investigator, would compromise the safety of the subject or the study. 2. Significant history or current evidence of chronic infectious disease, system disorder or organ dysfunction. 3. Presence of gastrointestinal disease or history of malabsorption within the last year. 4. History of psychiatric disorders occurring within the last two years that required hospitalization or medication. 5. Presence of a medical condition requiring regular treatment with prescription drugs. 6. Use of pharmacologic agents known to significantly induce or inhibit drug-metabolizing enzymes within 30 days prior to dosing. 7. Use within 7 days of dosing, or anticipated use during the study, or for 7 days after the last dose of sertraline any monoamine oxidase inhibitors (MAOIs). 8. Receipt of any drug as part of a research study within 30 days prior to dosing. 9. Donation or significant loss of whole blood (480 ml or more) within 30 days prior to dosing.

Age

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

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

Golestan University of Medical Sciences

Street address

Gorgan, Km 2 Sari Road

City

Gorgan

Postal code

Approval date

2016-01-21, 1394/11/01

Ethics committee reference number

ir.goums.rec.1395.184

Health conditions studied

1

Description of health condition studied

Antidepressant drugs

ICD-10 code

F32

ICD-10 code description

Healthy volunteers

Primary outcomes

1

Description

Drug plasma concentration

Timepoint

After intervention

Method of measurement

Blood sampling

Secondary outcomes

1

Description

Time to reach Cmax

Timepoint

After intervention

Method of measurement

Blood sampling

Intervention groups

1

Description

Single dose of two sertraline 50 mg tablets (100 mg) manufactured by Sobhandarou

Category

Treatment - Drugs

2

Description
Single dose of one sertraline 100 mg tablet manufactured by Sobhandarou
Category
Treatment - Drugs

3

Description
Single dose of one Zoloft (sertraline) 100 mg tablet manufactured by Pfizer
Category
Treatment - Drugs

Recruitment centers

1

Recruitment center
Name of recruitment center
Dialysis Center
Full name of responsible person
Mr. Ghezelsefloo
Street address
Shaheed Motahhari Hospital
City
Gonbade Kavous

Sponsors / Funding sources

1

Sponsor
Name of organization / entity
Sobhandarou Pharmaceutical Company
Full name of responsible person
Mrs. Loghmanifar
Street address
Central Office, West Fatemi Street
City
Tehran
Grant name
Grant code / Reference number
Is the source of funding the same sponsor organization/entity?
Yes
Title of funding source
Sobhandarou Pharmaceutical Company
Proportion provided by this source
100
Public or private sector
empty
Domestic or foreign origin
empty
Category of foreign source of funding
empty
Country of origin
Type of organization providing the funding
empty

Person responsible for general inquiries

Contact
Name of organization / entity
Gorgan Bioanalysis Center
Full name of responsible person
Dr. Hossein Amini
Position
Head of Center
Other areas of specialty/work
Street address
Golshahr Bolv., Golshahr 14, Aftabgardan Bulding, No. 6
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haminhplc@yahoo.com
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Person responsible for scientific inquiries

Contact
Name of organization / entity
Golestan University of Medical Sciences
Full name of responsible person
Dr. Hossein Amini
Position
Associtate Professor, Ph.D
Other areas of specialty/work
Street address
University Main Campus
City
Gorgan
Postal code
Phone
+98 17 3252 5972
Fax
Email
haminhplc@yahoo.com
Web page address

Person responsible for updating data

Contact

Sharing plan

Deidentified Individual Participant Data Set (IPD)
empty
Study Protocol
empty
Statistical Analysis Plan
empty
Informed Consent Form
empty
Clinical Study Report
empty

Analytic Code

empty

Data Dictionary

empty