Clinical Trial Protocol
Iranian Registry of Clinical Trials

16 Sep 2026

Comparative bioequivalence study of the Sertraline 100-mg Tablets manufactured by Modava Company with Sertraline brand tablets (Zoloft®) produced by Pfizer company

Protocol summary

Study aim

Demonstration of bioequivalence of Sertraline 100-mg tablets of Modava with Zoloft® tablet manufactured by Pfizer after single dose administration

Design

A single dose, randomized and crossover bioequivalence comparative study of Sertraline 100-mg tablets produced by Modava Company and Zoloft® produced by Pfizer Co. in 24 healthy male volunteers in two groups.

Settings and conduct

Study place and the place for blood sample analysis are the Drug Applied Research Center affiliated to Tabriz University of Medical Science, respectively. 24 healthy male volunteers will receive one of the two Sertraline 100-mg tablets test or reference in random sequence according to the randomization schedule. The interval between receiving the medicine (washout period) is 14 days, If the first sequence receives Iranian medicine, they will receive brand medicine. There will be no blinding in this study.

Participants/Inclusion and exclusion criteria

Inclusion criteria: Healthy male subjects in the age range of 18-60 years and BMI (Body Mass Index) of 18-30. Exclusion criteria: Subjects with Blood Pressure ≤ 90/60 mm/Hg or BP ≥ 140/90 mm/Hg; Any evidence of impairment of renal, hepatic, cardiac, lung or gastrointestinal function; a history of tuberculosis, epilepsy, asthma, diabetes, psychosis or glaucoma; being regular smoker.

Intervention groups

Intervention group 1: Sertraline 100-mg tablets manufactured by Modava Company is the test product. Intervention group 2: Zoloft® by Pfizer company is the reference product. In each period, 12 of 24 subjects will be given a single dose of this product. After the washout period, the volunteers are placed in the other group.

Main outcome variables

Peak Plasma Concentration (Cmax); Area under the concentration-time curve (AUC).

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20200407046981N46**
Registration date: **2022-10-20, 1401/07/28**
Registration timing: **prospective**

Last update: **2022-10-20, 1401/07/28**
Update count: **0**

Registration date

2022-10-20, 1401/07/28

Registrant information

Name

Fatima Molavi

Name of organization / entity

Country

Iran (Islamic Republic of)

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+98 41 3336 2700

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Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2022-12-22, 1401/10/01

Expected recruitment end date

2023-02-20, 1401/12/01

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Comparative bioequivalence study of the Sertraline 100-mg Tablets manufactured by Modava Company with Sertraline brand tablets (Zoloft®) produced by Pfizer company

Public title

Study of absorption and elimination rate of Sertraline 100-mg tablets in comparison with Sertraline brand tablets (Zoloft®).

Purpose

Treatment

Inclusion/Exclusion criteria

Inclusion criteria:

Healthy male volunteers in the age range of 18-60 years old The weight limit of each volunteer should be between 60 and 100 kg. Body mass index should be between18-30 All volunteers must be non-smokers They must be healthy in terms of liver, kidney, respiratory system, mental and other general health characteristics that will be assessed Candidates who have consented to the consent form

Exclusion criteria:

Known hypersensitivity or idiosyncratic reaction to Sertralin or any ingredients. Subjects with BP ≤ 90/60 mm/Hg or BP ≥ 140/90 mm/Hg. Taking any medicine during two week before dosing. Any effects of renal, hepatic, cardiac, pulmonary or gastrointestinal dysfunction Any history of tuberculosis, seizures, asthma, diabetes, insanity or glaucoma

Age

From **18 years** old to **60 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

To randomly assign people in two groups, 24 cards with numbers 1 to 24 will be used in closed envelopes that are arranged irregularly. Each candidate will pick up an envelope after entering the study, and numbers 1-12 will be in group A and numbers 13-24 will be in group B. Group A will receive intervention 1 and group B will receive intervention 2, and after the first period, the interventions of the both groups will be changed for the second period.

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 Tabriz University of Medical Science

Street address

Vice Chancellor for Research; Third floor; central building No. 2; Golgasht street

City

Tabriz

Province

East Azarbaijan

Postal code

5166614766

Approval date

2022-09-19, 1401/06/28

Ethics committee reference number

IR.TBZMED.REC.1401.562

Health conditions studied

1

Description of health condition studied

Bioequivalence study

ICD-10 code

ICD-10 code description

Primary outcomes

1

Description

Peak Plasma Concentration (Cmax)

Timepoint

0 (before dosing), 1, 2, 3, 4, 5, 6, 7, 8, 10, 12, 24, 48 and 72 hours after dosing

Method of measurement

High-performance liquid chromatography—mass spectrometry (HPLC-MS)

Secondary outcomes

1

Description

AUC (Area Under the Concentration-Time Curve)

Timepoint

0 (before dosing), 1, 2, 3, 4, 5, 6, 7, 8, 10, 12, 24, 48 and 72 hours after dosing

Method of measurement

Using non-compartmental model of Win-Nonlin Professional software version 3.2.A (Pharsight Corporation, USA) or SPSS

Intervention groups

1

Description
Intervention group 1: In this group, volunteers are given a single oral dose of Sertraline 100-mg tablets produced by Modava Co. (Domestic). In each period, 12 of 24 subjects will be given single oral dose of this product. After the washout period, the volunteers are placed in the Intervention group 2.

Category
Treatment - Drugs

2

Description
Intervention group 2: In this group, volunteers are given a single oral dose of Sertraline 100-mg tablets (Zoloft®), produced by Pfizer Company (Brand). In each period, 12 of 24 subjects will be given single oral dose of this product. After the washout period, the volunteers are placed in the Intervention group 1.

Category
Treatment - Drugs

Recruitment centers

1

Recruitment center

Name of recruitment center
Tabriz Drug Applied Research Center

Full name of responsible person
Dr Hamed Hamishehkar

Street address
Drug Applied Research Center, In front of Shahid Madani Hospital, Daneshghah Blvd, Tabriz, Iran

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Web page address
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Sponsors / Funding sources

1

Sponsor

Name of organization / entity
Modava Pharmaceutical Company

Full name of responsible person
Farrokh Rahimzadeh

Street address
Modava Pharmacy; Unit.5, No. 275, Shahid Beheshti Street

City
Tehran

Province
Tehran

Postal code
1514617714

Phone
+98 21 8817 4996

Email
r.otadi@modavaco.com

Web page address
http://www.modavapharma.com/

Grant name

Grant code / Reference number

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

Title of funding source
Modava 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
Tabriz University of Medical Sciences

Full name of responsible person
Fatima Molavi

Position
Non-Faculty Academic Position

Latest degree
Ph.D.

Other areas of specialty/work
Pharmaceutics

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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
There is no further information
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
Not applicable
Data Dictionary
Not applicable