

Clinical Trial Protocol

Iranian Registry of Clinical Trials

08 Jul 2026

Bioequivalence Study of Sertraline 50 mg tablet manufactured by Shafa Pharmaceutical and Zoloft manufactured by Pfizer in 24 Healthy Volunteers under fasting condition

Protocol summary

Study aim

Bioequivalence of Sertraline tablets of Shafa Pharmaceutical company with Zoloft tablets of Pfizer company (Germany)

Design

Bioequivalence study, Cross over, Double blinded. Randomization is done by Rand function of Excel software.

Settings and conduct

Sampling of volunteers is done in Kharazmi Plasma Center in Islamshahr. On the day of sampling, one 40 mg tablet of Sertraline manufactured by Shafa or Pfizer on two occasions and with a washout period of 14 days, will be administered orally with 240 ml of water to the volunteer. For example, if in the first phase he received the medicine made by Shafa company, he will receive the brand medicine two weeks later. In each phase, 5 cc of blood sample will be taken before drug administration and at times 0, 1, 2, 3, 4, 4.5, 5, 6, 7, 8, 10, 24, 48 and 72 hours after prescribing the medicine. Two weeks after the start of the study, the volunteer's cooperation in this research ends. The way to cooperate in these two weeks is that the drug is prescribed in the first day and after that 72 hours blood sampling is done at the mentioned times after washout period of two weeks the other drug is administered and blood samples will be taken at the same time.

Participants/Inclusion and exclusion criteria

Inclusion criteria: Healthy male or female volunteers between the ages of 18 and 55 with a body mass index (BMI) between 19 and 30 - People who are willing to sign an informed consent form. Exclusion criteria: history of heart disease

Intervention groups

First group: 12 people who take Shafa pharmaceutical tablets The second group: 12 people who take Pfizer pills on the same day

Main outcome variables

Plasma concentration and area under the curve of plasma concentration time of test and reference drug

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20220209053979N9**

Registration date: **2023-06-17, 1402/03/27**

Registration timing: **registered_while_recruiting**

Last update: **2023-06-17, 1402/03/27**

Update count: **0**

Registration date

2023-06-17, 1402/03/27

Registrant information

Name

Roya Talari

Name of organization / entity

Country

Iran (Islamic Republic of)

Phone

+98 21 8880 0892

Email address

talari_r@yahoo.com

Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2023-06-09, 1402/03/19

Expected recruitment end date

2023-06-23, 1402/04/02

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Bioequivalence Study of Sertraline 50 mg tablet manufactured by Shafa Pharmaceutical and Zoloft manufactured by Pfizer in 24 Healthy Volunteers under fasting condition

Public title

Bioequivalence of Sertraline 50 mg tablet manufactured by Shafa Pharmaceutical and Zoloft manufactured by Pfizer

Purpose

Other

Inclusion/Exclusion criteria**Inclusion criteria:**

Healthy male or female volunteers Body mass index (BMI) between 18 - 30 Volunteers who are willing to sign an informed consent form

Exclusion criteria:

Familial history of heart disease History of allergy to Sertraline or formulation components Taking any type of medicine in the 14 days before the start of the study Participation in any clinical study within 30 days prior to study

Age

From **18 years** old to **55 years** old

Gender

Both

Phase

Bioequivalence

Groups that have been masked

- Participant
- Data analyser

Sample size

Target sample size: **24**

More than 1 sample in each individual

Number of samples in each individual: **14**

5 millilitr blood sample is taken from each volunteer

Randomization (investigator's opinion)

Randomized

Randomization description

Using the rand option of the Excel software, the candidates are divided into two groups, and half of them will receive numbers 1-12 and get the test drug, and the other half will receive numbers 13-24 and will take the reference drug.

Blinding (investigator's opinion)

Double blinded

Blinding description

Before prescribing the medicine, the pills are removed from the blister by the prescriber, so the volunteer does not know which company's medicine is taking. Additionally, the tubes of the volunteers' samples are also coded, so the analyzer does not know which company's drug he is analyzing, so only the researcher and the prescriber know which company's drug is being prescribed.

Placebo

Not used

Assignment

Crossover

Other design features**Secondary Ids**

empty

Ethics committees**1****Ethics committee****Name of ethics committee**

Ethics Committee of Tehran University of Medical Science

Street address

Tehran University of Medical Science, 16 Azar St.,

City

Tehran

Province

Tehran

Postal code

1417713135

Approval date

2023-06-11, 1402/03/21

Ethics committee reference number

IR.TUMS.TIPS.REC.1402.036

Health conditions studied**1****Description of health condition studied**

A crossover bioequivalence study in 24 healthy volunteers

ICD-10 code**ICD-10 code description****Primary outcomes****1****Description**

Plasma concentration time profile, maximum plasma concentration, AUC

Timepoint

0, 1, 2, 3, 4, 4.5, 5, 6, 7, 8, 10, 24, 48, 72 hour after drug administration

Method of measurement

Liquid chromatography with mass spectrophotometry

Secondary outcomes**1****Description**

Calculation of pharmacokinetic parameters like Cmax, AUC of test and reference drug.

Timepoint

Same as primary outcome

Method of measurement

Pharmacokinetic parameters are calculated by excel.

Intervention groups

1

Description

Intervention group: Oral administration of one tablet of Sertraline 50 mg manufactured by Shafa Company to 12 healthy volunteers under fasting condition with 240 ml of water. Then 14 blood samples are taken from each volunteers at certain time

Category

Treatment - Drugs

2

Description

Intervention group: Oral administration of one tablet of Sertraline 50 mg manufactured by Pfizer Company to 12 healthy volunteers under fasting condition with 240 ml of water. Then 14 blood samples are taken from each volunteers at certain time.

Category

Treatment - Drugs

Recruitment centers

1

Recruitment center

Name of recruitment center

Kharazmi plasma center

Full name of responsible person

Sara Solgi

Street address

No. 13, Shehamat 1st Alley, Ali Ibn Abitalib St., Namaz Square,

City

Islamshahr

Province

Tehran

Postal code

3313679886

Phone

+98 21 5669 4726

Email

Info@kpcir.com

Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Shafa Pharmaceutical Company

Full name of responsible person

Dr.Razgardani

Street address

No. 13, Golberg Alley 4 East, Fakhar Moghadam St., Dadman St., Shahrek Gharb,

City

Tehran

Province

Tehran

Postal code

3197996423

Phone

+98 21 8836 8521

Email

info@shafadarou.org

Grant name

Grant code / Reference number

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

Yes

Title of funding source

Shafa 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

Kharazmi Plasma Center

Full name of responsible person

Roya Talari

Position

Executer

Latest degree

Ph.D.

Other areas of specialty/work

Medical Pharmacy

Street address

No. 13, Shehamat 1st Alley, Ali Ibn Abitalib St., Namaz Square,

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3313679886

Phone

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Email

talari_r@yahoo.com

Person responsible for scientific inquiries

Contact

Name of organization / entity

Kharazmi Plasma Center

Full name of responsible person

Roya Talari

Position

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Other areas of specialty/work

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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

The bioequivalence study data is completely confidential and according to the contract with Shafa Pharmaceutical Company, it should not be published anywhere.

Study Protocol

No - There is not 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

Person responsible for updating data**Contact****Name of organization / entity**

Kharazmi Plasma Center

Full name of responsible person

Roya Talari

Position

Executer

Latest degree

Ph.D.