Clinical Trial Protocol
Iranian Registry of Clinical Trials

16 Sep 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 Sertraliine 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 mililitr 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
Pharmacokientic 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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Person responsible for scientific inquiries

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Person responsible for updating data

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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