Clinical Trial Protocol
Iranian Registry of Clinical Trials

08 Jul 2026

In vivo Bioequivalence study of Sertraline 100 mg tablet manufactured by Reyhaneh Pharmaceutical Co. Compared to innovator Product Zoloft ®

Protocol summary

Study aim
In vivo Bioequivalence study of Sertraline 100 mg tablet manufactured by Reyhaneh Pharmaceutical Co. Compared to innovator Product Zoloft®

Design
In the present study 24 healthy male volunteer will enter randomly as two groups of twelve people. For randomization, the rand function of Excel software will be used. Each volunteer will receive a single dose of drug in two periods. In one period the test formulation and in another period the reference formulation (as blinded). Therefore, each volunteer will be his own "Control".

Settings and conduct
After administration of single dose of formulation to healthy volunteers at the relevant place in Tabriz University of Medical Sciences, the blood samples (5 ml in each time point) will be taken in predetermined time intervals up to 72 hours. After plasma separation, the samples will be stored in freezer until analysis . In this study the volunteer would not be aware of the formulation identity in each period and the medicine is given to the patient outside of its original packaging.

Participants/Inclusion and exclusion criteria
Inclusion criteria: General Health (Liver, Heart and Kidney), Age (18-60) Exclusion criteria: Smoking, History of cardiovascular disease, liver and kidney disease, Pregnancy, Alcohol and drug addiction, History of drug allergy

Intervention groups
Test group: Administrating the test product Control group: Administrating the innovator product In first period, one group of volunteers will receive single dose of test formulation (sertraline 100 mg tablet of Reyhaneh Pharmaceutical Co.) and the second group will receive a single dose of the reference formulation (Sertraline 100 mg tablet, Zoloft®) of same drug. After one week wash out period, by cross over design, the first group and second group will administer the reference and test formulations, respectively.

Main outcome variables
Drug plasma concentration

General information

Reason for update

Acronym

IRCT registration information
IRCT registration number: **IRCT20220211053992N1**
Registration date: **2022-05-29, 1401/03/08**
Registration timing: **prospective**

Last update: **2022-05-29, 1401/03/08**
Update count: **0**

Registration date
2022-05-29, 1401/03/08

Registrant information

Name
Hadi Valizadeh

Name of organization / entity

Country
Iran (Islamic Republic of)

Phone
+98 41 3334 8801

Email address
valizadehh@gmail.com

Recruitment status
Recruitment complete

Funding source

Expected recruitment start date
2022-06-21, 1401/03/31

Expected recruitment end date
2022-11-22, 1401/09/01

Actual recruitment start date
empty

Actual recruitment end date
empty

Trial completion date
empty

Scientific title
In vivo Bioequivalence study of Sertraline 100 mg tablet manufactured by Reyhaneh Pharmaceutical Co. Compared to innovator Product Zoloft ®

Public title
Investigating Bioequivalence of Sertraline Tablet

Purpose
Other

Inclusion/Exclusion criteria

Inclusion criteria:
General Health (Liver, Heart and Kidney) Age between 18 to 60 years

Exclusion criteria:
Smoking, , liver and kidney disease History of cardiovascular disease Pregnancy Alcohol and drug addiction History of drug allergy

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

Gender
Both

Phase
Bioequivalence

Groups that have been masked

- Participant

Sample size
Target sample size: **24**

Randomization (investigator's opinion)
Randomized

Randomization description
The order of receiving the test product or reference for each subject in each time period will be determined based on the randomization program. The randomization program will be developed using randomization software based on the number assigned to each subject. The number assigned to each subject will be based on the priority of being on the list of subjects for screening.

Blinding (investigator's opinion)
Single blinded

Blinding description
In this study, Volunteers participating will be blinded to the type of product they are taking in each period (test or reference product). In appearance, the two products are very similar and will be given to the volunteers for administration outside the original packaging.

Placebo
Not used

Assignment
Crossover

Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee
Ethics Committe ofTabriz University of Medical Sciences

Street address
No.2 Central Building 3rd Floor, Tabriz University of Medical Sciences, Daneshgah st.

City
Tabriz

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East Azarbaijan

Postal code
51664-14766

Approval date
2022-05-11, 1401/02/21

Ethics committee reference number
IR.TBZMED.REC.1401.145

Health conditions studied

1

Description of health condition studied

ICD-10 code

ICD-10 code description

Primary outcomes

1

Description
Plasma Drug Concentration

Timepoint
0.5-72 hours in predetermined time intervals after drug administration

Method of measurement
HPLC (High performance liquid chromatography)

Secondary outcomes

empty

Intervention groups

1

Description
Intervention group: Intervention group will receive one test drug product manufactured by Reyhaneh Co.. Blood samples will be taken from the volunteers for 72 hours at the mentioned times after drug administration and the concentration of drug in blood samples will be measured by liquid chromatography with mass spectroscopy detector

Category
Treatment - Drugs

2

Description

Control group: Control group will receive one reference drug product (Sertraline 100 mg tablet, Zoloft®). Blood samples will be taken from the volunteers for 72 hours at the mentioned times after drug administration and the concentration of drug in blood samples will be measured by liquid chromatography with mass spectroscopy detector

Category
Treatment - Drugs

Recruitment centers

1

Recruitment center

Name of recruitment center
Tabriz University of Medical Sciences, Faculty of Pharmacy

Full name of responsible person
Hadi Valizadeh

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Faculty of Pharmacy, University of Medical Sciences, Attar Neishaboori st, Golgasht.

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Sponsors / Funding sources

1

Sponsor

Name of organization / entity
Tabriz University of Medical Sciences

Full name of responsible person
Parviz Shahabi

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Grant name

Grant code / Reference number

Is the source of funding the same sponsor organization/entity?
No

Title of funding source
Reyhaneh 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
Tabriz University of Medical Sciences

Full name of responsible person
Hadi Valizadeh

Position
Professor

Latest degree
Ph.D.

Other areas of specialty/work
Medical Pharmacy

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Person responsible for scientific inquiries

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Position
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Latest degree
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Person responsible for updating data

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Sharing plan

Deidentified Individual Participant Data Set (IPD)
Undecided - It is not yet known if there will be a plan to make this available
Study Protocol
Undecided - It is not yet known if there will be a plan to make this available
Statistical Analysis Plan
Not applicable
Informed Consent Form
Undecided - It is not yet known if there will be a plan to make this available
Clinical Study Report
Undecided - It is not yet known if there will be a plan to make this available
Analytic Code
Not applicable
Data Dictionary
Not applicable