

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: Administering the test product Control group: Administering 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 Committee of Tabriz University of Medical Sciences

Street address

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

City

Tabriz

Province

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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Sponsors / Funding sources**1****Sponsor****Name of organization / entity**

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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**Contact****Name of organization / entity**

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Other areas of specialty/work

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

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Full name of responsible person

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Other areas of specialty/work

Medical Pharmacy

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City

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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