Clinical Trial Protocol
Iranian Registry of Clinical Trials

16 Sep 2026

A study to compare the relative bioavailability of paroxetine 20 mg tablets manufactured by Abian Pharmed and GlaxoSmithKline company (Paxil®) in 24 healthy adult volunteers under fasting conditions

Protocol summary

Study aim

The study aim is to evaluate the bioequivalence of paroxetine 20 mg tablets produced by two different pharmaceutical companies under fasting condition.

Design

This randomized, single-dose, two-way, crossover study is conducted to compare the pharmacokinetic of paroxetine and Paxil® tablets in 24 healthy adults volunteers. Volunteers will be sorted and receive a number from 1 to 24. In the first phase of the study, 12 volunteers will receive paroxetine manufactured by Abian Pharmed and the remaining 12 volunteers will receive Paxil® produced by GlaxoSmithKline company. The administered drugs will be replaced by each other in the second phase of the study.

Settings and conduct

The dose administration and subsequent sample collection will be performed in Shahid Motahhari hospital (Gonbade Kavous, Iran).

Participants/Inclusion and exclusion criteria

Inclusion criteria:18-55 years of age; good health at screening. Non-inclusion criteria: History of any drug hypersensitivity or intolerance; significant history or current evidence of chronic disease; receipt of any drug as part of a research study within 30 days prior to the present study.

Intervention groups

First intervention group: A single 20 mg oral dose of Paroxetine (1 tablet) manufactured by Abian Pharmed company to 12 subjects. Second intervention group: A single 20 mg oral dose of Paxil (1 tablet) manufactured by GlaxoSmithKline company to 12 subjects. Since in this study, the volunteers will receive both Test and Reference drugs, each volunteer will act as his own control.

Main outcome variables

Drug plasma concentration; Area under the plasma concentration-time curve

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20130626013776N36**
Registration date: **2021-04-13, 1400/01/24**
Registration timing: **prospective**

Last update: **2021-04-13, 1400/01/24**
Update count: **0**

Registration date

2021-04-13, 1400/01/24

Registrant information

Name

Hossein Amini

Name of organization / entity

Golestan University of Medical Sciences

Country

Iran (Islamic Republic of)

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Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2021-04-21, 1400/02/01

Expected recruitment end date

2021-12-22, 1400/10/01

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

A study to compare the relative bioavailability of paroxetine 20 mg tablets manufactured by Abian Pharmed and GlaxoSmithKline company (Paxil®) in 24 healthy adult volunteers under fasting conditions

Public title

Bioequivalence study of paroxetine 20 mg tablets

Purpose

Basic scienece

Inclusion/Exclusion criteria

Inclusion criteria:

18-55 years of age The subject is able and willing to provide signed informed consent The subject is available for the entire study period and is willing to adhere to protocol requirements as evidenced by written informed consent The subject has stable residence place and telephone Good health as determined by absence of clinically significant abnormalities in health assessments performed at screening

Exclusion criteria:

History of allergy or sensitivity to paroxetine History of any drug hypersensitivity or intolerance which, in the opinion of the investigator, would compromise the safety of the subject of the study Significant history or current evidence of chronic infectious disease, system disorder or organ dysfunction Presence of gastrointestinal disease or history of malabsorption within the last year History of a medical disorders occurring within the last year that required hospitalization or medication Use of pharmacologic agents known to significantly induce or inhibit drug-metabolizing enzymes within 30 days prior to dosing Receipt of any drug as part of a research study within 30 days prior to the present study Donation or significant loss of whole blood (480 ml or more) within 30 days prior to the present study

Age

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

Gender

Both

Phase

Bioequivalence

Groups that have been masked

No information

Sample size

Target sample size: **24**

More than 1 sample in each individual

Number of samples in each individual: **0**

A volume of 3 ml of blood is obtained in each sampling time through a venous cannula

Randomization (investigator's opinion)

Randomized

Randomization description

Each subject is identified by a number from 1 to 24. This number is allocated according to their entrance to volunteers' list in the screening day. Then, by using a prepared random number table, the participants are randomized into two sequences of Test/Reference and Reference/Test products

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 Golestan University of Medical Sciences

Street address

Falsafi Building, 5th Km of Sari road

City

Gorgan

Province

Golestan

Postal code

4934174515

Approval date

2021-01-24, 1399/11/05

Ethics committee reference number

IR.GOUMS.REC.1399.321

Health conditions studied

1

Description of health condition studied

.

ICD-10 code

ICD-10 code description

Primary outcomes

1

Description

Maximum Drug plasma concentration

Timepoint

At time zero and 1, 2, 3, 4, 5, 6, 7, 8, 10, 12, 24, 48 and 72 hours after drug administration

Method of measurement

Blood sampling and measurement of drug concentrations by high-performance liquid chromatographic method

2

Description

Area under plasma concentration-time curve

Timepoint

At time zero and 1, 2, 3, 4, 5, 6, 7, 8, 10, 12, 24, 48 and 72 hours after drug administration

Method of measurement

Blood sampling and measurement of drug concentrations by high-performance liquid chromatographic method

Secondary outcomes

1

Description

Plasma half-life

Timepoint

From the terminal 60 hours of plasma concentration-time profile

Method of measurement

Blood sampling and drug analysis by HPLC

Intervention groups

1

Description

Intervention group 1: Oral administration of a single 20 mg dose of paroxetine (1 tablet) manufactured by Abian Pharmed to 12 healthy volunteers under fasting condition in the morning of the experiment day. After 1 week, these 12 volunteers will receive the Brand product.

Category

Treatment - Drugs

2

Description

Intervention group 2: Oral administration of a single 20 mg dose of Paxil (1 tablet) manufactured by GlaxoSmithKline to 12 healthy volunteers under fasting condition in the morning of the experiment day. After 1 week, these 12 volunteers will receive the Test product.

Category

Treatment - Drugs

Recruitment centers

1

Recruitment center

Name of recruitment center

Dialysis Center, Shahid Motahhari Hospital

Full name of responsible person

Yahya Naserifard

Street address

Taleghani street

City

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Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Abian Pharmed Company

Full name of responsible person

Dr. Behzad Taghipour

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Grant name

Bioequivalence Study of Paroxetine

Grant code / Reference number

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

No

Title of funding source

Abian Pharmed 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

Gorgan University of Medical Sciences

Full name of responsible person

Hossein Amini

Position

Associate professor

Latest degree

Ph.D.

Other areas of specialty/work

Medical Pharmacy

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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
Data are confidential and need permission from the company.
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