Clinical Trial Protocol
Iranian Registry of Clinical Trials

17 Sep 2026

A study to compare the relative bioavailability of Raihaneh and Pfizer formulations of sildenafil 100 mg tablets in 24 healthy adult volunteers under fasting conditions

Protocol summary

Study aim

The study aims to compare the bioequivalence of sildenafil 100 mg tablets under fasting conditions

Design

This randomized, single-dose, two-way, crossover study is conducted to compare the pharmacokinetics of sildenafil and Viagra® tablets in 24 healthy adult volunteers. Volunteers will be sorted and receive a number from 1 to 24. In the first phase of the study, 12 volunteers will receive sildenafil manufactured by Raihaneh and the remaining 12 volunteers will receive Viagra® produced by Pfizer company. The administered drugs will be replaced to another group in the second phase of the study.

Settings and conduct

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

Participants/Inclusion and exclusion criteria

Inclusion criteria: aged 18-55 years; subject available for the entire study period; willingness to adhere to protocol requirements as evidenced by written informed consent; good health at screening. Exclusion criteria: History of use 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 100 mg oral dose of sildenafil (1 tablet) manufactured by Raihaneh company to 12 subjects. Second intervention group: A single 100 mg oral dose of Viagra (1 tablet) manufactured by Pfizer 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: **IRCT20130626013776N46**
Registration date: **2021-06-06, 1400/03/16**
Registration timing: **prospective**

Last update: **2021-06-06, 1400/03/16**
Update count: **0**

Registration date

2021-06-06, 1400/03/16

Registrant information

Name

Hossein Amini

Name of organization / entity

Golestan University of Medical Sciences

Country

Iran (Islamic Republic of)

Phone

+98 17 1442 1651

Email address

hamini@sbmu.ac.ir

Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2021-07-22, 1400/04/31

Expected recruitment end date

2022-02-20, 1400/12/01

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

A study to compare the relative bioavailability of Raihaneh and Pfizer formulations of sildenafil 100 mg tablets in 24 healthy adult volunteers under fasting conditions

Public title

Bioequivalence study of sildenafil 100 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 Willing to adhere to protocol requirements as evidenced by written informed consent The subject has a stable residence and telephone Good health as determined by lack of clinically significant abnormalities in health assessments performed at screening

Exclusion criteria:

History of allergy or sensitivity to sildenafil 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: **2**

In a crossover design, each person is its own control and receives two different interventions

Randomization (investigator's opinion)

Randomized

Randomization description

A pot sampling method will be used in this study. 12 papers are labeled "Reference Product" and 12 papers are written as "Test Product". The papers are then placed in sealed envelopes, and participants randomly select a paper and will be placed in the Reference or Test groups.

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, Sari Road Km 2

City

Gorgan

Province

Golestan

Postal code

4934174515

Approval date

2021-05-23, 1400/03/02

Ethics committee reference number

IR.GOUMS.REC.1400.055

Health conditions studied

1

Description of health condition studied

.

ICD-10 code

ICD-10 code description

Primary outcomes

1

Description

Drug plasma concentration

Timepoint

At time zero and 0.25, 0.5, 0.75, 1, 1.5, 2, 2.5, 3, 4, 6, 8, 10 and 12 h after drug administration

Method of measurement

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

2

Description

Area under plasma concentration-time curve

Timepoint

At time zero and 0.25, 0.5, 0.75, 1, 1.5, 2, 2.5, 3, 4, 6, 8,

10 and 12 h after drug administration

Method of measurement

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

Secondary outcomes

1

Description

Plasma half-life

Timepoint

From the terminal 6 hours of plasma concentration-time profile

Method of measurement

Blood sampling and drug analysis by high-performance liquid chromatography method

Intervention groups

1

Description

Intervention group: Oral administration of a single 100 mg dose of sildenafil (1 tablet) manufactured by Raihaneh to healthy volunteers under fasting condition in the morning of the experiment day

Category

Treatment - Drugs

2

Description

Intervention group: Oral administration of a single 100 mg dose of Viagra (1 tablet) manufactured by Pfizer to healthy volunteers under fasting condition in the morning of the experiment day

Category

Treatment - Drugs

Recruitment centers

1

Recruitment center

Name of recruitment center

Dialysis Center, S. Motahhari Hospital

Full name of responsible person

Yahya Naserifard

Street address

Taleghani Street

City

Gonbade Kavous

Province

Golestan

Postal code

4916817693

Phone

+98 17 3252 5972

Fax

+98 17 3252 5972

Email

haminhplc@yahoo.com

Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Raihaneh Pharmaceuticals

Full name of responsible person

Dr. Maryam kefayati

Street address

Head Office: No 17, Fifth floor, Pazhouheshgah 2 alley, Ahmad Qusayr Street, Shahid Beheshti Street

City

Tehran

Province

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Postal code

1517975911

Phone

+98 21 8866 2585

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+98 21 8978 1005

Email

info@rayhanehpharma.com

Web page address

https://rayhanehpharma.com/

Grant name

Bioequivalence Study of Sildenafil

Grant code / Reference number

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

No

Title of funding source

Raihaneh Pharmaceuticals

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