

Clinical Trial Protocol

Iranian Registry of Clinical Trials

22 Jul 2026

In vivo fasted-state bioequivalence study of Sildenafil 100 mg tablet manufactured by Farnoush Darou Teb Co. compared with innovator product

Protocol summary

Study aim

In vivo fasted-state bioequivalence study of Sildenafil 100 mg tablet

Design

The clinical trial has control and test groups with crossover, randomized design, without blinding. Twenty-four healthy male volunteers will participate randomly in the study as two twelve-person groups. Each volunteer will receive a single oral dose of drug in fasted state in two periods. Each volunteer will be his own "Control". To randomly assign participants in groups, lottery method will be used.

Settings and conduct

After oral administration of one 100-mg tablet by eligible candidate who entered in the study, the blood samples will be collected in predetermined time intervals up to 24 hours. After plasma separation by centrifuge, samples will be stored in freezer -4 degrees centigrade until analysis. The concentration of drug will be measured by liquid chromatography with Mass-spectroscopy detector. The study will be performed in Faculty of Pharmacy, Tabriz University of Medical Sciences without blinding.

Participants/Inclusion and exclusion criteria

Inclusion criteria: General Health (in terms of Liver, Heart and Kidney), Age (18-59 years old) Exclusion criteria: Smoking, History of cardiovascular, liver and kidney disease, Alcohol and drug addiction, History of drug allergy.

Intervention groups

Intervention group will receive a single oral dose of test product (Sildenafil 100 mg tablet of Farnoush Darou Teb) and Control group will receive a single dose of reference product (Viagra 100 mg tablet of Pfizer, Belgium). Blood samples will be taken for 24 hours. In both groups, breakfast and lunch will be served two and six hours after drug administration, respectively). After a week, the test and control group will be exchanged and will receive

the drug of second manufacturer.

Main outcome variables

Drug plasma concentration

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20210519051345N28**

Registration date: **2023-05-01, 1402/02/11**

Registration timing: **prospective**

Last update: **2023-05-01, 1402/02/11**

Update count: **0**

Registration date

2023-05-01, 1402/02/11

Registrant information

Name

Parvin Zakeri-Milani

Name of organization / entity

Country

Iran (Islamic Republic of)

Phone

+98 41 3334 8801

Email address

pzakeri@tbzmed.ac.ir

Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2023-05-21, 1402/02/31

Expected recruitment end date

2023-12-21, 1402/09/30

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

In vivo fasted-state bioequivalence study of Sildenafil 100 mg tablet manufactured by Farnoush Darou Teb Co. compared with innovator product

Public title

Investigating the in vivo bioequivalence of Sildenafil 100 mg

Purpose

Other

Inclusion/Exclusion criteria**Inclusion criteria:**

General Health (in terms of Liver, Heart and Kidney)

Exclusion criteria:

Smoking History of cardiovascular disease, liver and kidney disease Alcohol and drug addiction History of drug allergy

Age

From **18 years** old to **59 years** old

Gender

Male

Phase

Bioequivalence

Groups that have been masked*No information***Sample size**Target sample size: **24****Randomization (investigator's opinion)**

Randomized

Randomization description

To randomly assign participants in two groups, 24 cards with numbers 1 to 24 will be used in closed envelopes that are arranged irregularly. Each candidate will pick up an envelope. Numbers 1-12 will be in group A and numbers 13-24 will be in group B. Group A will receive intervention 1 and group B will receive intervention 2, and after the first period, the interventions of both groups will change for the second period.

Blinding (investigator's opinion)

Not blinded

Blinding description**Placebo**

Not used

Assignment

Crossover

Other design features**Secondary Ids**

empty

Ethics committees1**Ethics committee**

Name of ethics committee

Biomedical Research Committee, 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

2023-04-03, 1402/01/14

Ethics committee reference number

IR.TBZMED.REC.1402.024

Health conditions studied1**Description of health condition studied**

In the present study, the products will be administered to healthy volunteers.

ICD-10 code**ICD-10 code description****Primary outcomes**1**Description**

Plasma concentration of drug

Timepoint

Before drug administration and 0.5-24 hours after drug administration in the following time intervals:0.5, 1,1.5, 2, 2.5, 3, 4, 6, 8, 10, 12, 24 h

Method of measurement

HPLC (High performance liquid chromatography)

Secondary outcomes

empty

Intervention groups1**Description**

Intervention group: Intervention group will receive a single oral dose of test product (Sildenafil 100 mg tablet manufactured by Farnoush Darou Teb Co.) in fasted state. Blood samples will be collected for 24 hours at the mentioned times after drug administration and the samples will be stored in freezer until analysis. Breakfast and lunch will be served two and six hours after drug administration, respectively. After a week, the test and control group will be exchanged and will receive the drug of second manufacturer.

Category

Treatment - Drugs

2

Description

Control group: Control group will receive a single oral dose of reference product (Sildenafil 100 mg tablet manufactured by Pfizer, Belgium) in fasted state. Blood samples will be collected for 24 hours at the mentioned times after drug administration and the samples will be stored in freezer until analysis. Breakfast and lunch will be served two and six hours after drug administration, respectively. After a week, the test and control group will be exchanged and will receive the drug of second

Category

Treatment - Drugs

Recruitment centers

1

Recruitment center

Name of recruitment center

Faculty of Pharmacy Tabriz University of Medical Sciences

Full name of responsible person

Parvin Zakeri-Milani

Street address

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

City

Tabriz

Province

East Azarbaijan

Postal code

51664-14766

Phone

+98 41 3334 8801

Email

pzakeri@tbzmed.ac.ir

Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Tabriz University of Medical Sciences

Full name of responsible person

Parviz Shahabi

Street address

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

City

Tabriz

Province

East Azarbaijan

Postal code

51664-14766

Phone

+98 41 3334 8801

Email

shahabip@tbzmed.ac.ir

Grant name

Grant code / Reference number

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

Yes

Title of funding source

Tabriz University of Medical Sciences

Proportion provided by this source

10

Public or private sector

Public

Domestic or foreign origin

Domestic

Category of foreign source of funding

empty

Country of origin

Type of organization providing the funding

Academic

2

Sponsor

Name of organization / entity

Farnoush Darou Teb

Full name of responsible person

Mehrdad Saghari Khodaparast

Street address

No. 14, 22 Bahman Alley, Ghodoosi St., Mirdamad Blvd.

City

Tehran

Province

Tehran

Postal code

۱۵۴۹۹۳۵۴۱۶

Phone

+98 21 2291 9375

Email

Franoush.Teb@pharma.ir

Grant name

Grant code / Reference number

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

Yes

Title of funding source

Farnoush Darou Teb

Proportion provided by this source

90

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

Parvin Zakeri-Milani

Position

Professor

Latest degree

Ph.D.

Other areas of specialty/work

Medical Pharmacy

Street address

Faculty of Pharmacy, Golgasht st., Attar Neishabouri st.

City

Tabriz

Province

East Azarbaijan

Postal code

51664-14766

Phone

+98 41 3334 8801

Fax

+98 41 3334 4798

Email

pzakeri@tbzmed.ac.ir

pzakeri@tbzmed.ac.ir

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

Tabriz University of Medical Sciences

Full name of responsible person

Parvin Zakeri-Milani

Position

Professor

Latest degree

Ph.D.

Other areas of specialty/work

Medical Pharmacy

Street address

Faculty of Pharmacy, Golgasht st., Attar Neishabouri st.

City

Tabriz

Province

East Azarbaijan

Postal code

51664-14766

Phone

+98 41 3334 8801

Fax

+98 41 3334 4798

Email

pzakeri@tbzmed.ac.ir

Person responsible for scientific inquiries**Contact****Name of organization / entity**

Tabriz University of Medical Sciences

Full name of responsible person

Parvin Zakeri-Milani

Position

Professor

Latest degree

Ph.D.

Other areas of specialty/work

Medical Pharmacy

Street address

Faculty of Pharmacy, Golgasht st., Attar Neishabouri st.

City

Tabriz

Province

East Azarbaijan

Postal code

51664-14766

Phone

+98 41 3334 8801

Fax

+98 41 3334 4798

Email**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

Undecided - It is not yet known if there will be a plan to make this available

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