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)

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+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 committees

1

Ethics committee
Name of ethics committee
Biomedical Research Committe, 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 studied

1

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 groups

1

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 Medicl Sciences, Golgasht st., Attar Neishaboori st.

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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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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.

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Province
Tehran

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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
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Person responsible for scientific inquiries

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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
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