Clinical Trial Protocol
Iranian Registry of Clinical Trials

09 Jun 2026

Comparative bioequivalence study of Sildenafil 100 mg tablets of Dorsa Pharmaceutical Co. and Pfizer in 24 healthy male under fasting.

Protocol summary

Study aim

This study was performed to compare the pharmacokinetics and in-vivo parameters of the formulation of 100 mg Sildenafil tablet of Dorsa Pharmaceutical Co. as a test product with the formulation of 100 mg Sildenafil tablet of Pfizer As a reference product and evaluation of biological equivalence of these two formulations is done.

Design

Randomized, single-dose, crossover comparative bioequivalence study of Sildenafil 100 mg of Dorsa Pharmaceutical Co. and Pfizer in 24 healthy male under fasting.

Settings and conduct

The clinical phase is open-labelled and in each period, volunteers will receive a single dose of the treatment in the Farabi Clinic (Eslamshahr, Tehran). 2 dosing periods will be separated by a 7-day washout period.

Participants/Inclusion and exclusion criteria

Inclusion Criteria: Healthy subjects (male) between 20 – 45 years of age and Body Mass Index (BMI) within 15% of normal range according to the accepted normal values between 18.5 and 30 (inclusive), calculated as kg/m2. Subjects with no significant diseases or clinically significant abnormal findings during screening, medical history, clinical examination and laboratory evaluations.

Intervention groups

Intervention group (test): Sildenafil 100 mg Tablet, produced by Dorsa Pharmaceutical Co. is the test product. In each period, 12 of 24 subjects will be given a single oral dose of this product. Intervention group (Reference): Viagra 100 mg tablet, produced by Pfizer is the reference product. In each period, 12 of 24 subjects will be given a single oral dose of this product.

Main outcome variables

Peak Plasma Concentration

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20180620040164N45**
Registration date: **2023-05-09, 1402/02/19**
Registration timing: **retrospective**

Last update: **2023-05-09, 1402/02/19**
Update count: **0**

Registration date

2023-05-09, 1402/02/19

Registrant information

Name

Behzad Montaha Sangari

Name of organization / entity

Noor research and educational institute (Tavan)

Country

Iran (Islamic Republic of)

Phone

+98 21 6600 7026

Email address

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Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2022-11-07, 1401/08/16

Expected recruitment end date

2022-11-21, 1401/08/30

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title
Comparative bioequivalence study of Sildenafil 100 mg tablets of Dorsa Pharmaceutical Co. and Pfizer in 24 healthy male under fasting.

Public title
Bioequivalence study of Sildenafil 100 mg tablet in 24 healthy male under fasting conditions

Purpose
Treatment

Inclusion/Exclusion criteria

Inclusion criteria:
Healthy subjects (male) between 20 – 45 years of age and Body Mass Index (BMI) within 15% of normal range according to the accepted normal values between 18.5 and 30 (inclusive), calculated as kg/m2. Subjects with no significant diseases or clinically significant abnormal findings in laboratory evaluations. Subjects with normal vital signs. Subjects who agree with patient consent form.

Exclusion criteria:
Allergic reaction to sildenafil Acute or chronic diseases of the cardiovascular, bronchopulmonary, neuroendocrine systems, and also diseases of the gastrointestinal tract, liver, kidneys and blood, eye disease The presence of mental disorders, including a history. Dehydration due to diarrhea, vomiting or other reason within the last 24 hours before taking the drug Consumption of nitric oxide donor drugs, organic nitrates or other nitrite forms during the 30 days before drug administration in study period I. Systolic blood pressure (SBP) <100 mm Hg or ≥ 130 mm Hg Diastolic blood pressure (DBP) <60 mm Hg or ≥ 85 mm Hg. Smoking more than 10 cigarettes per day and could not tolerate cigarette cessation during each clinical period; Subjects who has used any drug including prescription or Over-The-Counter (OTC) drugs within 1 days prior to the start of the study and might need drug intake during study period; History of alcohol or drug abuse within 2 years before the start of the study; Heavy drinker of caffeine, grapefruit juice or caffeinated drinks or who are on special diet (such as vegetarians) or do exertional physical activity; A history of difficulty with donating blood or donation of more than 500 ml blood within 7 days prior to the start of the study.

Age
From **20 years** old to **45 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
The randomization schedule will be generated with https://www.sealedenvelope.com/simple-randomiser/v1/lists. A 2*2 block randomization list is created. We have 12 blocks and within each two volunteer's number (allocated after screening) for all 24 volunteers. According to this list, a treatment sequence of Test/Reference or Reference/Test will be given to each volunteer.

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 Shahid Beheshti University of Medical Sciences

Street address
Niayesh Highway, Valiasr Ave, Tehran, Iran

City
Tehran

Province
Tehran

Postal code
1996835113

Approval date
2021-08-10, 1400/05/19

Ethics committee reference number
IR.SBMU.PHARMACY.REC.1400.116

Health conditions studied

1

Description of health condition studied
Bioequivalence investigation of the generic Dorsa Pharmaceutical Co. Sildenafil 100 mg Tablet with brand Viagra Pfizer Tablet.

ICD-10 code

ICD-10 code description

Primary outcomes

1

Description
Peak Plasma Concentration (Cmax)

Timepoint
During 2 months after intervention

Method of measurement
Using non-compartmental model of Win-Nonlin Professional software version 3.2.A (Pharsight Corporation, USA)

Secondary outcomes

1

Description
AUC (Area Under the Concentration-Time Curve)
Timepoint
During 2 months after intervention
Method of measurement
using non-compartmental model of Win-Nonlin Professional software version 3.2.A (Pharsight Corporation, USA)

Intervention groups

1

Description
Intervention group:(test):Sildenafil 100 mg Tablet, produced by Dorsa Pharmaceutical Co. is the test product. In each period, 12 of 24 subjects will be given single oral dose of this product.
Category
Treatment - Drugs

2

Description
Intervention group: (refrence): Viagra 100 mg Tablet, produced by Pfizer is the refrence product. In each period, 12 of 24 subjects will be given single oral dose of this product.
Category
Treatment - Drugs

Recruitment centers

1

Recruitment center
Name of recruitment center
Hakim Farabi Clinic
Full name of responsible person
Ebrahim Siahpoosh
Street address
No. 57, Shemshad alley, Sallor city
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Email
mina.hasanabadi@yahoo.com

Sponsors / Funding sources

1

Sponsor
Name of organization / entity
Dorsa Pharmaceutical Co.
Full name of responsible person
Amir esmael Saghafinia
Street address
Teimori-Shahid Salehi Blv-Fanavari Tarash Tower-8th floor
City
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Province
Tehran
Postal code
1459965204
Phone
+98 21 5461 2000
Email
info@dorsadarou.com
Grant name
Grant code / Reference number
Is the source of funding the same sponsor organization/entity?
Yes
Title of funding source
Dorsa 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
Noor Research & Development Institute
Full name of responsible person
Ali Aghaei
Position
Master
Latest degree
Master
Other areas of specialty/work
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Person responsible for updating data

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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
It's not specified yet
Study Protocol
Undecided - It is not yet known if there will be 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