Clinical Trial Protocol
Iranian Registry of Clinical Trials

09 Jun 2026

In- Vivo Bioequivalence study of Tadalafil tablet 5 mg Mofid Pharma with brand drugs (CIALIS® 5 mg, Lilly USA) in Iranian healthy volunteers.

Protocol summary

Study aim

In- Vivo Bioequivalence study of Tadalafil tablet 5 mg Mofid Pharma with brand drugs (CIALIS® 5 mg, Lilly USA) in Iranian healthy volunteers.

Design

Single dose, randomized, two sequences, two period crossover with a washout period.

Settings and conduct

This study will be conducted in single-dose, cross-over, and fasting, and on two sets of healthy volunteers. The study will be conducted in two periods of 72 hours. The interval between these two periods, which is called the wash-out time, is determined by the half-life of the drug plasma, which according to scientific sources should be at least 5 to 7 half-life of the drug in the case of the drug under study. The plan will take a week to clean up the drug, given the biological half-life of the drugs in the drug form. In the first round, candidates are divided into two groups, and the first group receives a test tablet and the second group receives similar tablets. Blood samples will be taken by the volunteer by the technician immediately after taking the drug, and the preparation steps of the samples, including plasma separation and drug extraction, are performed to analyze the amount of drug on them. All steps of the study will done in Simin Baspar Teyf Gostar Co.

Participants/Inclusion and exclusion criteria

The ages and BMIs of participants must be in the range of 18-60 and 18-28 respectively. Inclusion criteria: Hypersensitivity , History of drug or alcohol use and liver diseases.

Intervention groups

Single dose Tadalafil 5 mg Tablets Mofid Pharmaceuticals Company with brand drugs (CIALIS® 5 mg, Lilly USA)

Main outcome variables

Determination of blood drug concentration

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20200105046010N39**
Registration date: **2021-09-12, 1400/06/21**
Registration timing: **registered_while_recruiting**

Last update: **2021-09-12, 1400/06/21**
Update count: **0**

Registration date

2021-09-12, 1400/06/21

Registrant information

Name

Javad Shokri

Name of organization / entity

Country

Iran (Islamic Republic of)

Phone

+98 41 3661 4125

Email address

shokri.j@gmail.com

Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2021-08-05, 1400/05/14

Expected recruitment end date

2022-03-05, 1400/12/14

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

In- Vivo Bioequivalence study of Tadalafil tablet 5 mg Mofid Pharma with brand drugs (CIALIS® 5 mg, Lilly USA) in Iranian healthy volunteers.

Public title
In-vivo Bioequivalence study of Tadalafil tablet with brand drugs (CIALIS Lilly USA)
Purpose
Treatment
Inclusion/Exclusion criteria
Inclusion criteria:
General health Body mass index(18-28) Informed consent Age(18-60)
Exclusion criteria:
Smoking A history of cardiovascular disease A history of liver & kidney disease Pregnancy Alcohol & Drug addiction Hypersensitivity to the drug
Age
From **18 years** old to **60 years** old
Gender
Both

Phase
Bioequivalence
Groups that have been masked

- Participant

Sample size
Target sample size: **24**
Randomization (investigator's opinion)
Randomized
Randomization description
For this purpose, the name of total volunteers (24 people) are written on paper pieces and placed to the bottle after wrapped into the aluminum foils. the papers Withrow from bottle randomly. the first and second 12 names randomly taken from the bottle are considered as group A and group B respectively.
Blinding (investigator's opinion)
Single blinded
Blinding description
Iranian Tadalafil tablets and Tadalafil brand are removed from their packaging by the executor and placed in similar and coded cans. Volunteers will not be informed about receiving the brand or test medications
Placebo
Not used
Assignment
Crossover
Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee
Name of ethics committee
Ethics Committee, Tabriz University of Medical Sciences
Street address
Third floor of TUMS (Tabriz University of Medical Sciences) central building, Dneshgah St. Tabriz, Iran
City
Tabriz
Province
East Azarbaijan
Postal code
5166614766
Approval date
2021-05-17, 1400/02/27
Ethics committee reference number
IR.TBZMED.REC.1400.162

Health conditions studied

1

Description of health condition studied
Bio equivalence test
ICD-10 code
ICD-10 code description

Primary outcomes

1

Description
Determination of blood drug concentration.
Timepoint
Sampling times in this study will be 0, 1, 2, 2:30, 3, 3:20, 3:40, 4, 4:20, 4: 40, 5, 6, 8, 10, 12, 24, 48, 72 hours After prescribing the tablet.
Method of measurement
High Performance Liquid Chromatography with tandem mass spectroscopy detector

Secondary outcomes

empty

Intervention groups

1

Description
Intervention group: will receive one test drug tablet (Tadalafil tablet 5 mg Mofid Pharma Pharmaceuticals). Blood samples will be taken from the volunteers for 72 hours at the mentioned times after drug administration and the concentration of Tadalafil in blood samples will be measured by liquid chromatography with mass spectroscopy detector.
Category
Treatment - Other

2

Description
Control group: Control group: will receive one test drug table (CIALIS® 5 mg, Lilly USA Pharmaceuticals). Blood samples will be taken from the volunteers for 72 hours at

the mentioned times after drug administration and the concentration of Tadalafil in blood samples will be measured by liquid chromatography with mass spectroscopy detector.

Category
Treatment - Other

Recruitment centers

1

Recruitment center

Name of recruitment center
Simin Baspar Teyf Gostar Company

Full name of responsible person
Javad Shokri

Street address
No.48, Ferdos Street

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Tabriz

Province
East Azarbaijan

Postal code
5167874434

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+98 41 3384 2724

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+98 41 3384 2724

Email
Shokri.j@gmail.com

Sponsors / Funding sources

1

Sponsor

Name of organization / entity
Mofid Pharmaceutical Co.

Full name of responsible person
Mohammad Reza Zargarzadeh

Street address
Tehran Shahid Beheshti Street Ahmad Qusayr Street, Pazhouheshgah(2) alley, fifth floor

City
Tehran

Province
Tehran

Postal code
3361658369

Phone
+98 21 8817 5119

Fax
+98 26 4422 8116

Email
info@mofidpharma.com

Grant name

Grant code / Reference number

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

Title of funding source
Mofid 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
Persons

Person responsible for general inquiries

Contact

Name of organization / entity
Tabriz University of Medical Sciences

Full name of responsible person
Javad Shokri

Position
Professor

Latest degree
Ph.D.

Other areas of specialty/work
Medical Pharmacy

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Faculty of Pharmacy, University of Medical Sciences, Daneshgah Street,Tabriz East Azerbayjan

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Person responsible for scientific inquiries

Contact

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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
These date are as secure between researcher and related industries
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
Yes - There is a plan to make this available
Title and more details about the data/document
Only protocol and methods of study are sharable
When the data will become available and for how long
Only protocol and methods of study are shareable.
To whom data/document is available
Pharmaceutical and medical sciences researchers
Under which criteria data/document could be used
Projects information's for any publications is not allowed.
From where data/document is obtainable
By email to the project manager (shokri.j@gmail.com)
What processes are involved for a request to access data/document
This information is confidential and is at the disposal of the project sponsor. Upon request, the information will be provided to the applicant by the contractor's email after the
Comments