Clinical Trial Protocol
Iranian Registry of Clinical Trials

22 Sep 2026

in- Vivo Bioequivalence study of Finasteride tablet 5 mg Aburaihan Pharma (FINIDE® 5 mg FC.Tablets, Aburaihan, Iran) with brand drug (PROSCAR® 5 mg, FC. Tablets, MSD,Germany) in Iranian healthy volunteers.

Protocol summary

Study aim

in- Vivo Bioequivalence study of Finasteride tablet 5 mg Aburaihan Pharma (FINIDE® 5 mg FC.Tablets, Aburaihan, Iran) with brand drug (PROSCAR® 5 mg, FC. Tablets, MSD,Germany) in Iranian healthy volunteers.

Design

In-vivo bioequivalence study of Finasteride tablet 5 mg Aburaihan Pharma. in compared with reference drug (PROSCAR® 5 mg, FC. Tablets, MSD,Germany). The single blind, Cross-over, two period, two groups (Intervention and control) and randomized (paper lottery randomization method) study with one week wash-out time.

Settings and conduct

This study is carried out in Simin Baspar Tayf-Gostar Company, Tabriz, Iran. The study population is 24 healthy Iranian volunteers.This study is a single blind study and by taking out the drugs from the existing packaging, the volunteers will not know the time of receiving the test drug and the brand. This study is a cross over study that is performed in two time periods of 24 hours with a two-week wash-out period.

Participants/Inclusion and exclusion criteria

Inclusion criteria: Age between 18-55 years, body mass index (BMI) in the range of 18-28. Exclusion criteria: History of heart, kidney and liver disease, Pregnancy, Drug addiction, Smoking

Intervention groups

Single dose Finasteride tablet 5 mg Aburaihan Pharma. Control group: brand drugs (PROSCAR® 5 mg, FC. Tablets, MSD,Germany)

Main outcome variables

Plasma drug concentration

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20200105046010N54**
Registration date: **2022-02-11, 1400/11/22**
Registration timing: **registered_while_recruiting**

Last update: **2022-02-11, 1400/11/22**
Update count: **0**

Registration date

2022-02-11, 1400/11/22

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

2022-02-03, 1400/11/14

Expected recruitment end date

2022-08-05, 1401/05/14

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title
in- Vivo Bioequivalence study of Finasteride tablet 5 mg Aburaihan Pharma (FINIDE® 5 mg FC.Tablets, Aburaihan, Iran) with brand drug (PROSCAR® 5 mg, FC. Tablets, MSD,Germany) in Iranian healthy volunteers.

Public title
In-vivo Bioequivalence Test ofFinasteride tablets with brand drug (PROSCAR® 5 mg, FC. Tablets, MSD,Germany)

Purpose
Treatment

Inclusion/Exclusion criteria

Inclusion criteria:
General health Body mass index between18-28 Informed consent Being at the age of 18-55 years old

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 **55 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, A 24- persons group will be selected and divided to two 12-persons groups randomly. The names of all volunteers will be written on paper pieces and wrapped in aluminum foils. The first 12 papers will randomly be withdrawn from bottle will be selected as group A and others will be categorized in group B.

Blinding (investigator's opinion)
Single blinded

Blinding description
Candidates are not aware of receiving the test drug or brand one. In a one-blind study, information that could distort the test result is hidden from the candidates, but the person in charge of the test is aware of it. Test and Brand drugs 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 drug.

Placebo
Not used

Assignment
Crossover

Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee
Ethics Committee of Tabriz University of Medical Sciences

Street address
Third floor; Central building; Tabriz University of Medical Sciences; Dneshgah St.

City
Tabriz

Province
East Azarbaijan

Postal code
5166614766

Approval date
2022-01-12, 1400/10/22

Ethics committee reference number
IR.TBZMED.REC.1400.1045

Health conditions studied

1

Description of health condition studied
Bio equivalence test

ICD-10 code

ICD-10 code description

Primary outcomes

1

Description
Plasma drug concentration

Timepoint
Sampling times in this study will be 0, 0:30, 1, 1:30, 2, 2:30, 3, 4, 6, 8, 10, 24 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: One test tablet (Finasteride tablet 5 mg produced by Aburaihan Pharma.) will be received. Blood samples will be taken for 24 hours at the mentioned times after drug administration and the concentration of the drug in Plasma samples will be measured by liquid chromatography with mass spectroscopy detector

Category
Treatment - Other

2

Description
Control group: One Reference tablet (PROSCAR® 5 mg, FC. Tablets, MSD,Germany) will be received. Blood samples will be taken for 24 hours at the mentioned times after drug administration and the concentration of Finasteride in plasma 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
Full name of responsible person
Javad Shokri
Street address
No.48, Ferdos square
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Sponsors / Funding sources

1

Sponsor
Name of organization / entity
Aburayhan Pharmaceutical Company
Full name of responsible person
Mortaza Sobhani Niya
Street address
Tehran - corner of Tehranpars three ways in front of Shahr Hotel, No. 1
City
Tehran
Province
Tehran
Postal code
1654613111
Phone
+98 21 7770 7173
Email
info@aburaihan.com
Grant name
Grant code / Reference number
Is the source of funding the same sponsor organization/entity?
Yes
Title of funding source
Aburayhan Pharmaceutical Company
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
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Person responsible for updating data

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Others

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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

All information and data of the study will remain secured based on the agreement established between researcher and drug producer.

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

The access to data will be possible after finishing of project (almost 6 months after receiving of IRCT Code).

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

These information are confidential and be under disposal of the project's contractor. Upon request, the information will be accessed to the applicant by the Executor's email after receiving contractor's consent.

Comments