

Clinical Trial Protocol

Iranian Registry of Clinical Trials

22 Sep 2026

Comparative bioequivalence study of Finasteride 5 mg Tablet of Karen Pharma and Food Supplement Co. and PROSCAR® of ORGANON as reference in 24 healthy male under fasting.

Protocol summary

Study aim

This study will be performed to compare the pharmacokinetics and invivo parameters of Finasteride 5 mg Tablet formulation as a test product with Proscar 5 mg Tablet formulation as a reference product to evaluate the bioequivalence.

Design

Non-blinded, randomized, crossover in vivo bioequivalence study in 24 healthy males under fasting conditions. Block randomization for a treatment sequence of Test/Reference or Reference/Test is used.

Settings and conduct

In each period, volunteers will receive a single dose of the treatment in the Noor Research and Development Institute (Tarasht, 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.
Exclusion criteria: Subjects with known allergy to the products tested.

Intervention groups

Intervention group 1: Proscar 5 mg Tablet, produced by Iran Hormone Pharmaceutical Co. is the test product. In each period, 12 of 24 subjects will be given a single oral dose of this product. After 7-day wash-out period the intervention 2 will be given to these subjects.
Intervention group 2: Proscar 5 mg Tablet, produced by ORGANON is the reference product. In each period, 12 of 24 subjects will be given a single oral dose of this product. After 7-day wash-out period the intervention 1 will be given to these subjects.

Main outcome variables

Peak Plasma Concentration

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20180620040164N55**

Registration date: **2024-01-24, 1402/11/04**

Registration timing: **prospective**

Last update: **2024-01-24, 1402/11/04**

Update count: **0**

Registration date

2024-01-24, 1402/11/04

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

2024-03-02, 1402/12/12

Expected recruitment end date

2024-03-16, 1402/12/26

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty	
Scientific title	Comparative bioequivalence study of Finasteride 5 mg Tablet of Karen Pharma and Food Supplement Co. and PROSCAR® of ORGANON as reference in 24 healthy male under fasting.
Public title	Comparative in vivo evaluation of 2 Finasteride 5 mg Tablet formulations.
Purpose	Treatment
Inclusion/Exclusion criteria	Inclusion criteria: Healthy subjects (male) between 20 – 45 years of age. 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. Exclusion criteria: Subjects with known allergy to Tested Product. Subjects with no significant diseases or clinically significant abnormal findings during screening, medical history, clinical examination and laboratory evaluations. Smoking more than 10 cigarettes per day and could not tolerate cigarette cessation during each clinical period. 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. Married candidates are advised to strictly refrain from sexual intercourse during the test and in the sampling interval.
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/lits . 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, School of Pharmacy, Nursing & Midwifery - Shahid Beheshti University of medical sciences Street address Niayesh Highway, Valiasr Ave, Tehran, Iran City Tehran Province Tehran Postal code 1996835113 Approval date 2024-01-15, 1402/10/25 Ethics committee reference number IR.SBMU.PHARMACY.REC.1402.217
Health conditions studied	1 Description of health condition studied Prostatic coccidioidomycosis ICD-10 code B38.81 ICD-10 code description Prostatic coccidioidomycosis
Primary outcomes	1 Description Peak Plasma Concentration (Cmax) Timepoint 16 blood samples will be withdrawn pre-dose and at 0.5, 1, 1.5, 2, 2.5, 3, 3.5, 4, 4.5, 5, 6, 8, 10, 12 and 24 hours 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 16 blood samples will be withdrawn pre-dose and at 0.5, 1, 1.5, 2, 2.5, 3, 3.5, 4, 4.5, 5, 6, 8, 10, 12 and 24 hours Method of measurement Using non-compartmental model of Win-Nonlin

Intervention groups

1

Description

Intervention group1:(Test) Finasteride 5 mg tablet, produced by Iran Hormone Pharmaceutical Co. is the test product. In each period, 12 of 24 subjects will be given single oral dose of this product. After 7-day wash-out period the intervention 2 will be given to these subjects.

Category

Treatment - Drugs

2

Description

Intervention group 2: (Test) Finasteride 5 mg tablet produced by ORGANON is the reference product. In each period, 12 of 24 subjects will be given single oral dose of this product. After 7-day wash-out period the intervention 1will be given to these subjects.

Category

Treatment - Drugs

Recruitment centers

1

Recruitment center

Name of recruitment center

Noor Research & Development Institute (Tavan)

Full name of responsible person

Behzad Montaha Sangari

Street address

Sharif Innovation Station, North Habibollah Street, Hosseini Square, Teymouri Street, Tarasht.

City

Teran

Province

Tehran

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1459926609

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info@tavaninstitute.ir

Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Iran Hormone Pharmaceutical Co.

Full name of responsible person

Mehdi Amani

Street address

Km 11 Karaj Makhsous Road, Tehran, Iran

City

Tehran

Province

Tehran

Postal code

1399813611

Phone

+98 21 4490 5517

Email

info@iranhormone.com

Grant name

Grant code / Reference number

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

Yes

Title of funding source

Iran Hormone Pharmaceutical Co.

Proportion provided by this source

100

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

Industry

Person responsible for general inquiries

Contact

Name of organization / entity

Noor Research & Development Institute

Full name of responsible person

Behzad Montaha sangari

Position

Master

Latest degree

Medical doctor

Other areas of specialty/work

Medical Pharmacy

Street address

Sharif innovation station, North Habibollah Street, Hosseini Square, Teymouri Street, Tarasht.

City

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Person responsible for scientific inquiries

Contact

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Tavan Institute

Full name of responsible person

Seyed Mohsen Foroutan

Position

Principal investigator

Latest degree

Ph.D.

Other areas of specialty/work

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Person responsible for updating data

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Full name of responsible person

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Position

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Latest degree

Medical doctor

Other areas of specialty/work

Medical Pharmacy

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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

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

No - There is not a plan to make this available