

Clinical Trial Protocol

Iranian Registry of Clinical Trials

05 Aug 2026

Comparative bioequivalence study of Tamsulosin 0.4 mg ER Capsule of Dorsa Pharmaceutical Co. and "Omnic of astellas in 24 healthy male under fasting.

Protocol summary

Study aim

This study will be performed to compare the pharmacokinetics and invivo parameters of Tamsulosin 0.4 mg ER Capsule formulation as a test product with Omnic® capsule formulation as a reference product and to evaluate the bioequivalence of these two formulations.

Design

Randomized, single-dose, crossover comparative bioequivalence study of Tamsulosin 0.4 mg ER Capsule of Dorsa Pharmaceutical Co. and astellas in 24 healthy male under fasting condition.

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). Two dosing periods will be separated by a 7-day washout period.

Participants/Inclusion and exclusion criteria

Inclusion criteria: Healthy Subjects should be between 20-45 years old and their BMI should be in the range of 15% of the normal range (kg per square meter) 18.5-30; Subjects with no significant diseases or clinically significant abnormal findings during screening, medical history, clinical examination and laboratory evaluations. Non-inclusion criteria: History of known allergies to test products; Smokers who smoke more than 10 cigarettes a day and have trouble not smoking during each clinical study period; Subjects who has used any drug including prescription or Over-The-Counter (OTC) drugs within 14 days prior to the start of the study and might need drug intake during study period.

Intervention groups

Intervention group: Tamsulosin 0.4 mg ER Capsule , 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. Control group: Omnic Capsule, produced by astellas. 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: **IRCT20180620040164N26**

Registration date: **2022-05-17, 1401/02/27**

Registration timing: **registered_while_recruiting**

Last update: **2022-05-17, 1401/02/27**

Update count: **0**

Registration date

2022-05-17, 1401/02/27

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

2022-05-07, 1401/02/17

Expected recruitment end date

2022-05-19, 1401/02/29

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Comparative bioequivalence study of Tamsulosin 0.4 mg ER Capsule of Dorsa Pharmaceutical Co. and Omnic of astellas in 24 healthy male under fasting.

Public title

Clinical study to compare the in vivo parameters of 2 Tamsulosin 0.4 mg ER Capsule formulations

Purpose

Treatment

Inclusion/Exclusion criteria**Inclusion criteria:**

Healthy Subjects should be between 20-45 years old. Subjects with BMI in the range of 15% of the normal range (kg per square meter) 18.5-30. Subjects with no significant diseases or clinically significant abnormal findings during screening, medical history, clinical examination and laboratory evaluations. Subjects must have normal vital signs. Subjects agree to all clinical study requirements based on clinical study guidelines that have been approved by accepting the informed consent form.

Exclusion criteria:

History of known allergies to test products. Subject with a history of neoplastic disease (cancer), stroke, chronic seizures or major neurological disorder, clinically significant endocrine, gastrointestinal, cardiovascular, hematological, hepatic, immunological, renal, respiratory, or genitourinary abnormalities or diseases. Smokers who smoke more than 10 cigarettes a day and have trouble not smoking during each clinical study period. Subjects who has used any drug including prescription or Over The-Counter (OTC) drugs within 14 days prior to the start of the study and might need drug intake during study period. People who have a history of alcoholism or alcohol consumption in the past 2 years. Heavy drinker of caffeine, grapefruit juice or caffeinated drinks. who are on special diet (such as vegetarians). Who 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 **18 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/lis>. 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

2021-12-14, 1400/09/23

Ethics committee reference number

IR.SBMU.PHARMACY.REC.1400.250

Health conditions studied**1****Description of health condition studied**

Bioequivalence investigation of the generic Dorsa Pharmaceutical Co. Tamsulosin 0.4 mg ER capsule with Omnic astellas brand capsule.

ICD-10 code**ICD-10 code description****Primary outcomes****1****Description**

Peak Plasma Concentration (Cmax)

Timepoint

14 blood samples up to 48 hours and sample analysis during 3 months after intervention

Method of measurement

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

Email
mina.hasanabadi@yahoo.com

Secondary outcomes

1

Description

AUC (Area Under the Concentration-Time Curve)

Timepoint

14 blood samples up to 48 hours and sample analysis
during 3 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: Tamsulosin 0.4 mg Capsule,
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. After 7-day wash-out
period the control intervention will be given to these
subjects.

Category

Treatment - Drugs

2

Description

Control group: Omnic 0.4 mg Capsule, produced by
astellas 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 test intervention will be
given to these subjects.

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, in front of Sallor town

City

Tehran

Province

Tehran

Postal code

4635314588

Phone

+98 21 9253 5647

Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Dorsa Pharmaceutical Co.

Full name of responsible person

Amir Esmael Saghafeinia

Street address

8th floor; -Fanavari Tarasht Tower; Teimori; Shahid
Salehi Blvd

City

Tehran

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

Pharmacy

Street address

Sharif innovation station, North Habibollah Street,
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Person responsible for scientific inquiries

Contact

Name of organization / entity
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

Contact

Name of organization / entity

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Full name of responsible person
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Latest degree
Master
Other areas of specialty/work
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Hosseini Square, Teymouri Street, Tarasht
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1459926609
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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 undetermined 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