Clinical Trial Protocol
Iranian Registry of Clinical Trials

07 Nov 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)

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Iran (Islamic Republic of)

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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/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
2021-12-14, 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)

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 refrence 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
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
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
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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
Medical Pharmacy
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Sharif innovation station, North Habibollah Street, Hosseini Square, Teymoury Street, Tarasht
City
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Postal code
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Email
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Person responsible for updating data

Contact
Name of organization / entity
Tavan 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, Hosseini Square, Teymoury Street, Tarasht
City
Tehran
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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 undetermind 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