# Clinical Trial Protocol
# Iranian Registry of Clinical Trials

07 Nov 2026

## Comparative bioequivalence study of Tamsulosin 0.4 mg ER Capsule of Cosar 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 Cosar 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 Body Mass Index (BMI) within 15% of normal range 18.5 and 30 (inclusive), calculated as kg/m2; Subjects with no significant diseases or clinically significant abnormal findings during screening, medical history, clinical examination and laboratory evaluations. Exclusion 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 Cosar 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: **IRCT20180620040164N28**
Registration date: **2022-06-08, 1401/03/18**
Registration timing: **prospective**

Last update: **2022-06-08, 1401/03/18**
Update count: **0**

**Registration date**
2022-06-08, 1401/03/18

**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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+98 21 6600 7026

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**Recruitment status**
**Recruitment complete**

**Funding source**

**Expected recruitment start date**
2022-06-14, 1401/03/24

**Expected recruitment end date**
2022-06-28, 1401/04/07

**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 Cosar 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. Body Mass Index (BMI) within 15% of normal range 18.5 and 30 (inclusive), calculated as kg/m2. 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 Block randomization was done at the site: https://www.sealedenvelope.com/simple-randomiser/v1/lists. By the aid of this method, all possible assignments within a block is calculated. Then, the blocks are randomly chosen to assign the subject numbers into groups with equal sample size. The numbers are assigned to subjects according to the subjects' study entrance order during screening period. The groups include 2 Test/Reference or Reference/Test sequence of drug administration with non-blinded allocation.
**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 School of Pharmacy and Nursing & Midwifery- Shahid Beheshti University of Medica
**Street address**
Niayesh Highway, Valiasr Ave, Tehran, Iran
**City**
Tehran
**Province**
Tehran
**Postal code**
1996835113
**Approval date**
2022-05-24, 1401/03/03
**Ethics committee reference number**
IR.SBMU.PHARMACY.REC.1401.034

## Health conditions studied

### 1

**Description of health condition studied**
**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 Cosar 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
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**Province**
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**Email**
mina.hasanabadi@yahoo.com

## Sponsors / Funding sources

### 1

**Sponsor**
**Name of organization / entity**
Cosar pharmaceutical Co.
**Full name of responsible person**
Dr. Mohammad Soltani
**Street address**
Darougar street, 17km Old Way Karaj-Tehran
**City**
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**Province**
Tehran
**Postal code**
1415519871
**Phone**
+98 21 4492 1074
**Email**
info@cosarpharm.com
**Grant name**
**Grant code / Reference number**
**Is the source of funding the same sponsor organization/entity?**
Yes
**Title of funding source**
Cosar 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
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Master
**Latest degree**
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**Other areas of specialty/work**
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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**
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