

Clinical Trial Protocol

Iranian Registry of Clinical Trials

05 Aug 2026

Bioequivalence study of Tamsulosin 0.4mg capsule manufactured by Rayhaneh Co. compared with innovator product

Protocol summary

Study aim

In vivo fasted-state bioequivalence study of Tamsulosin 0.4 mg capsule

Design

The clinical trial has control and test groups with crossover, randomized design, without blinding. Twenty-four healthy male volunteers will participate randomly in the study as two twelve-person study groups. Each volunteer will receive a single oral dose of drug in fasted state in two periods. To randomly assign participants in two groups, the lottery method will be used.

Settings and conduct

After oral administration of one 0.4 mg capsule, the blood samples will be collected in predetermined time intervals up to 48 hours. The samples will be stored in freezer -4 degrees centigrade until analysis. The concentration of drug in blood samples will be measured by liquid chromatography equipped with mass spectroscopy detector. The study will be performed in Faculty of Pharmacy, Tabriz University of Medical Sciences. This study will be conducted without blinding.

Participants/Inclusion and exclusion criteria

Inclusion criteria: General Health (in terms of Liver, Heart and Kidney), Age (18-59 years old) Exclusion criteria: Smoking, Pregnancy, Alcohol and drug addiction, History of drug allergy.

Intervention groups

Intervention group will receive a single oral dose of test product (Tamsulosin 0.4 mg capsule of Rayhaneh) and Control group will receive a single dose of reference product (Tamsulosin 0.4 mg capsule of Pfizer, Switzerland). Blood samples will be taken for 48 hours and the plasma will be stored in freezer until analysis. In both groups, breakfast and lunch will be served two and six hours after drug administration, respectively. After a week, the test and control group will be exchanged and will receive the drug of second manufacturer.

Main outcome variables

Drug plasma concentration

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20220211053992N7**

Registration date: **2023-05-13, 1402/02/23**

Registration timing: **prospective**

Last update: **2023-05-13, 1402/02/23**

Update count: **0**

Registration date

2023-05-13, 1402/02/23

Registrant information

Name

Hadi Valizadeh

Name of organization / entity

Country

Iran (Islamic Republic of)

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+98 41 3334 8801

Email address

valizadehh@gmail.com

Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2023-06-20, 1402/03/30

Expected recruitment end date

2024-03-19, 1402/12/29

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Bioequivalence study of Tamsulosin 0.4mg capsule manufactured by Rayhaneh Co. compared with innovator product		Tabriz	
Public title		Province	
Investigating the in vivo bioequivalence of Tamsulosin 0.4 mg		East Azarbaijan	
Purpose		Postal code	
Other		51664-14766	
Inclusion/Exclusion criteria		Approval date	
Inclusion criteria:		2023-03-06, 1401/12/15	
General Health (in terms of Liver, Heart and Kidney) Age (18-59 years old)		Ethics committee reference number	
Exclusion criteria:		IR.TBZMED.REC.1402.023	
Smoking Pregnancy Alcohol and drug addiction History of drug allergy		Health conditions studied	
Age		<u>1</u>	
From 18 years old to 59 years old		Description of health condition studied	
Gender		In the present study, the products will be administered to healthy volunteers.	
Male		ICD-10 code	
Phase		ICD-10 code description	
Bioequivalence		Primary outcomes	
Groups that have been masked		<u>1</u>	
No information		Description	
Sample size		Plasma concentration of drug	
Target sample size: 24		Timepoint	
Randomization (investigator's opinion)		In 1, 2, 3, 4, 5, 6, 8, 10, 12, 24 and 48 hours after drug administration	
Randomized		Method of measurement	
Randomization description		HPLC (High performance liquid chromatography)	
To randomly assign participants in two groups, 24 cards with numbers 1 to 24 will be used in closed envelopes that are arranged irregularly. Each candidate will pick up an envelope. Numbers 1-12 will be in group A and numbers 13-24 will be in group B. Group A will receive intervention 1 and group B will receive intervention 2, and after the first period, the interventions of both groups will change for the second period.		Secondary outcomes	
Blinding (investigator's opinion)		empty	
Not blinded		Intervention groups	
Blinding description		<u>1</u>	
Placebo		Description	
Not used		Intervention group: Intervention group will receive a single oral dose of test product (Tamsulosin 0.4 mg capsule manufactured by Rayhaneh Co.) in fasted state. Blood samples will be collected for 48 hours at the mentioned times after drug administration and the concentration of drug in blood samples will be stored in freezer until analysis. Breakfast and lunch will be served two and six hours after drug administration, respectively. After a week, the test and control group will be exchanged and will receive the drug of second manufacturer.	
Assignment		Category	
Crossover		Treatment - Drugs	
Other design features		<u>2</u>	
Secondary Ids		Description	
empty		Control group: Control group will receive a single oral dose of reference product (Tamsulosin 0.4 mg tablet manufactured by Pfizer, Switzerland) in fasted state. Blood samples will be collected for 48 hours at the	
Ethics committees			
<u>1</u>			
Ethics committee			
Name of ethics committee			
Ethics Committee of Tabriz University of Medical Sciences			
Street address			
No.2 Central Building 3rd Floor, Tabriz University of Medical Sciences, Daneshgah st.			
City			

mentioned times after drug administration and the concentration of drug in blood samples will be stored in freezer until analysis. Breakfast and lunch will be served two and six hours after drug administration, respectively. After a week, the test and control group will be exchanged and will receive the drug of second manufacturer.

Category

Treatment - Drugs

Recruitment centers**1****Recruitment center****Name of recruitment center**

Faculty of Pharmacy, Tabriz University of Medical Sciences

Full name of responsible person

Hadi Valizadeh

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Faculty of Pharmacy, Tabriz University of Medical Sciences, Attar Neishaboori st. Golgasht St

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Sponsors / Funding sources**1****Sponsor****Name of organization / entity**

Tabriz University of Medical Sciences

Full name of responsible person

Parviz Shahabi

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No.2 Central Building 3rd Floor, Tabriz University of Medical Sciences, Daneshgah st.

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Email

shahabip@tbzmed.ac.ir

Grant name**Grant code / Reference number****Is the source of funding the same sponsor organization/entity?**

No

Title of funding source

Tabriz University of Medical Sciences

Proportion provided by this source

10

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**

Academic

2**Sponsor****Name of organization / entity**

Rayhaneh Pharmaceutical Co.

Full name of responsible person

Ahmad Rezvani

Street address

No.5, Parvaneh St., Jalal Al Ahmad St.

City

Tehran

Province

Tehran

Postal code

1439915481

Phone

+98 21 8822 5561

Email

info@rayhanehpharma.com

Grant name**Grant code / Reference number****Is the source of funding the same sponsor organization/entity?**

Yes

Title of funding source

Rayhaneh Pharmaceutical Co.

Proportion provided by this source

90

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**

Tabriz University of Medical Sciences

Full name of responsible person

Hadi Valizadeh

Position

Professor

Latest degree

Ph.D.

Other areas of specialty/work

Medical Pharmacy

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Person responsible for scientific inquiries**Contact****Name of organization / entity**

Tabriz University of Medical Sciences

Full name of responsible person

Hadi Valizadeh

Position

Professor

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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Position

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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

Undecided - It is not yet known if there will be a plan to make this available

Statistical Analysis Plan

Not applicable

Informed Consent Form

Undecided - It is not yet known if there will be a plan to make this available

Clinical Study Report

Undecided - It is not yet known if there will be a plan to make this available

Analytic Code

Not applicable

Data Dictionary

Undecided - It is not yet known if there will be a plan to make this available