Clinical Trial Protocol
Iranian Registry of Clinical Trials

10 Jun 2026

Bioequivalence study of Dutasteride/tamsulosin 0.5/0.4 mg capsule manufactured by Tasnim Co versus originator brand (Jalyn) manufactured by (GlaxoSmithCline plc (GSK) in fasting condition in healthy volunteers

Protocol summary

Study aim

Bioequivalence study of Dutasteride / Tamsulosin 0.4/0.5 mg capsule manufactured by Tasnim Co. versus originator brand (Jalyn) manufactured by GlaxoSmithCline plc (GSK) in fasting condition in healthy volunteers.

Design

Bioequivalence study, crossover, single-blinded, 24 healthy volunteers. Simple randomization was used for randomization

Settings and conduct

The study is a single-blinded (Volunteers), cross-over and fasting, and on two series of healthy volunteers. The study will be done in two periods (48h). The interval between these two periods is a week. In the first round of the study, the candidates were divided into two groups the first group received a test capsule and the second group received a brand capsule. Blood samples are collected immediately before and after drug administration by volunteers. Then, drug extraction is done and samples are ready for analysis. Sampling is performed in Radin laboratory in Tabriz.

Participants/Inclusion and exclusion criteria

Inclusion Criteria: General Health (Liver, Heart, and Kidney), Body Mass Index (18-28), Informed consent, Age (18-55 years old) Exclusion criteria: Smoking, History of cardiovascular disease, History of liver and kidney disease, Alcohol and drug addiction, History of allergy to Dutasteride / Tamsulosin

Intervention groups

Intervention group 1: Jalyn 0.4/0.5 mg capsule manufactured by GlaxoSmithCline plc (GSK) as a reference Intervention group 2: Avolocin 0.4/0.5mg manufactured by Tasnim Co. as a test

Main outcome variables

Maximum drug concentration, Time to reach maximum drug concentration

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20200105046010N91**
Registration date: **2024-01-16, 1402/10/26**
Registration timing: **prospective**

Last update: **2024-01-16, 1402/10/26**
Update count: **0**

Registration date

2024-01-16, 1402/10/26

Registrant information

Name

Javad Shokri

Name of organization / entity

Country

Iran (Islamic Republic of)

Phone

+98 41 3661 4125

Email address

shokri.j@gmail.com

Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2024-01-21, 1402/11/01

Expected recruitment end date

2025-01-20, 1403/11/01

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title
Bioequivalence study of Dutasteride/tamsulosin 0.5/0.4 mg capsule manufactured by Tasnim Co versus originator brand (Jalyn) manufactured by (GlaxoSmithCline plc (GSK) in fasting condition in healthy volunteers

Public title
Bioequivalence study of Dutasteride/tamsulosin 0.5/0.4 mg capsule

Purpose
Treatment

Inclusion/Exclusion criteria

Inclusion criteria:
General Health (Liver, Heart, and Kidney) Body Mass Index (18-28) Informed consent Age (18-55 years old)

Exclusion criteria:
Smoking History of cardiovascular disease History of liver and kidney disease Alcoholism and Narcoticism History of allergy to Dutasteride and tamsulosin

Age
From **18 years** old to **55 years** old

Gender
Both

Phase
Bioequivalence

Groups that have been masked

- Participant

Sample size
Target sample size: **24**

Randomization (investigator's opinion)
Randomized

Randomization description
People in the mentioned age group are invited to participate through the advertisement. People are then checked for health and healthy volunteers are identified. Each candidate is assigned a number from 1 to 24. The numbers are written on a plastic ball, poured into a container, and mixed. The balls are then removed randomly from the container. The first 12 no.s are considered as (first sequence: Tasnim's medicine) and the second 12 no.s are considered as (second sequence: originator brand recipient). The volunteers don't have any information about taking the test drug or brand drug

Blinding (investigator's opinion)
Single blinded

Blinding description
This study is a single-blinded clinical trial (volunteers). Test and Originator brand's capsules are removed from their packaging by the executor and placed in similar and coded cans. Volunteers will not be informed about receiving the brand or test dosage form.

Placebo
Not used

Assignment
Crossover

Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee
Tabriz University of Medical Sciences ethics committe

Street address
Research and technology deputy,3rd floor, No 2 Central Building, Tabriz University of Medical Sciences, Golgasht Street

City
Tabriz

Province
East Azarbaijan

Postal code
5165665931

Approval date
2023-12-18, 1402/09/27

Ethics committee reference number
IR.TBZMED.REC.1402.703

Health conditions studied

1

Description of health condition studied
This study is performed on healthy volunteers and drug concentration in plasma is determined.

ICD-10 code

ICD-10 code description

Primary outcomes

1

Description
Drug plasma concentration

Timepoint
0, 1, 2, 3, 3.5, 4, 4.5, 5, 5.5, 6, 6.5, 7, 7.5, 8, 10, 12, 24 and 48h after drug administration

Method of measurement
Liquid Chromatography Mass-Mass

Secondary outcomes

1

Description
Time to reach maximum plasma concentration

Timepoint
After intervention

Method of measurement
Time to reach the maximum drug concentration in plasma is recorded.

2

Description
Extent of absorption

Timepoint

After intervention

Method of measurement

Calculation of area under curve of concentration -time

Intervention groups

1

Description

Intervention group: single dose, one oral capsul Jalyn 0.4/0.5 mg manufactured by GSK as a reference product. after washout period, the volunteers receive Avolocin 0.4/0.5mg capsule manufactured by Tasnim Co.

Category

Treatment - Drugs

2

Description

Intervention group: Single dose, one oral Avolocin 0.4/0.5mg capsule manufactured by Tasnim company as a test product. after the washout period, the volunteers receive Jalyn 0.4/0.5 mg manufactured by GSK.

Category

Treatment - Drugs

Recruitment centers

1

Recruitment center

Name of recruitment center

Radin laboratory

Full name of responsible person

Javad Shokri

Street address

No.22, first floor, Moalem st., Abureihan St

City

Tabriz

Province

East Azarbaijan

Postal code

5154995671

Phone

+98 914 313 5843

Fax

Email

shokri.j@gmail.com

Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Tasnim company

Full name of responsible person

Nazanin Nami moghadam

Street address

Tasnim Building, No. 3, 14th East Street, Beyhaqi Street, Argentina Square

City

Tehran

Province

Tehran

Postal code

۱۵۱۵۶۶۷۹۱۱

Phone

+98 21 8817 4810

Email

info@tasnimpharma.com

Grant name

Grant code / Reference number

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

Yes

Title of funding source

Tasnim company

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

Tabriz University of Medical Sciences

Full name of responsible person

Javad Shokri

Position

Professor

Latest degree

Ph.D.

Other areas of specialty/work

Medical Pharmacy

Street address

No 4, 10th Ave. Boostan Street, Roshdieh

City

Tabriz

Province

East Azarbaijan

Postal code

5155935357

Phone

+98 41 3661 4125

Fax

Email

shokri.j@gmail.com

Person responsible for scientific inquiries

Contact

Name of organization / entity

Tabriz University of Medical Sciences

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Position
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Person responsible for updating data

Contact

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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
These data are as secure between researchers and related industries.

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