Clinical Trial Protocol
Iranian Registry of Clinical Trials

07 Nov 2026

Bioequivalence study of Lansoprazole 30 mg Capsule of Dorsa Pharmaceutical Co. and Agopton of Takeda as reference in 24 healthy male under fasting.

Protocol summary

Study aim

This study will be performed to compare the pharmacokinetics and invivo parameters of Lansoprazole 30 mg Capsule formulation as a test product with Agopton 30 mg Capsule formulation as a reference product and to evaluate the bioequivalence of these two formulations.

Design

Non-blinded, randomized, crossover in vivo bioequivalence study in 24 healthy males under fasting conditions. Block randomization for a treatment sequence of Test/Reference or Reference/Test is used.

Settings and conduct

In each period, volunteers will receive a single dose of the treatment in the Noor Research and Development Institute (Tarasht, Tehran). 2 dosing periods will be separated by a 21-day washout period.

Participants/Inclusion and exclusion criteria

Inclusion Criteria: Healthy subjects (male) between 18 – 45 years of age and Body Mass Index (BMI) between 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 sensitivity to the tested product History of specific disease or unusual values in laboratory tests and general clinical examination

Intervention groups

Intervention group 1: Lansoprazole 30 mg 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. Intervention group 2: Agopton 30 mg Capsule, produced by Takeda 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: **IRCT20180620040164N66**
Registration date: **2024-06-22, 1403/04/02**
Registration timing: **prospective**

Last update: **2024-06-22, 1403/04/02**
Update count: **0**

Registration date

2024-06-22, 1403/04/02

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

2024-08-06, 1403/05/16

Expected recruitment end date

2024-08-20, 1403/05/30

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title
Bioequivalence study of Lansoprazole 30 mg Capsule of Dorsa Pharmaceutical Co. and Agopton of Takeda as reference in 24 healthy male under fasting.

Public title
Comparative in vivo evaluation of 2 Lansoprazole 30 mg Capsule formulations.

Purpose
Treatment

Inclusion/Exclusion criteria

Inclusion criteria:
Healthy subjects (male) between 18 – 45 years of age and Body Mass Index (BMI) between 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 with normal vital signs. Subjects who agree with patient consent form.

Exclusion criteria:
History of known sensitivity to the tested product History of specific disease or unusual values in laboratory tests and general clinical examination Hypertension (blood pressure in a standing position and after at least 5 minutes of rest, systole greater than or equal to 140 mmHg and diastole greater than or equal to 90 mmHg) Smoking more than 10 cigarettes a day Loss of more than 500 ml of blood in less than 7 days.

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 numbers (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,School of Pharmacy,Nursing&Midwifery-Shahid Beheshti University of medical sciences

Street address
Niayesh Highway, Valiasr Ave, Tehran, Iran

City
Tehran

Province
Tehran

Postal code
1996835113

Approval date
2024-05-27, 1403/03/07

Ethics committee reference number
IR.SBMU.PHARMACY.REC.1403.036

Health conditions studied

1

Description of health condition studied
Eosinophilic esophagitis

ICD-10 code
K20.0

ICD-10 code description
Eosinophilic esophagitis

Primary outcomes

1

Description
Peak Plasma Concentration (Cmax)

Timepoint
14 blood samples will be withdrawn pre-dose and at 0.5, 1, 1.5, 2, 2.5, 3, 3.5, 4, 4.5, 5, 6, 8 and 12 hours 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 will be withdrawn pre-dose and at 0.5, 1, 1.5, 2, 2.5, 3, 3.5, 4, 4.5, 5, 6, 8 and 12 hours 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 1: Lansoprazole 30 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 07-day wash-out period the intervention 2 will be given to these subjects.
Category
Treatment - Drugs

2

Description
Intervention group 2: Agopton 30 mg Capsule, produced by Takeda is the reference product. In each period, 12 of 24 subjects will be given single oral dose of this product. After 21-day wash-out period the intervention 1 will be given to these subjects.
Category
Treatment - Drugs

Recruitment centers

1

Recruitment center
Name of recruitment center
Noor Research & Development Institute (Tavan)
Full name of responsible person
Behzad Montaha Sangari
Street address
Sharif Innovation Station, North Habibollah Street, Hosseini Square, Teymoury Street, Tarasht.
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info@tavaninstitute.ir

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
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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
Behzad Montaha Sangari
Position
CEO(Chef Executive Officer)
Latest degree
Medical doctor
Other areas of specialty/work
Medical Pharmacy
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Person responsible for scientific inquiries

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Person responsible for updating data

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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
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