Clinical Trial Protocol
Iranian Registry of Clinical Trials

16 Sep 2026

Comparative bioequivalence study of Amlodipine 10 mg plus Valsartan 160 mg film coated tablet of ACTOVERCO and NOVARTIS in 24 healthy male under fasting

Protocol summary

Study aim

This study will be performed to compare the pharmacokinetics and invivo parameters of Amlodipine 10 mg + Valsartan 160 mg film coated tablet formulation as a test product with EXFORGE® tablet formulation as a reference product and to evaluate the biocompatibility of these two formulations.

Design

Randomized, single-dose, crossover comparative bioequivalence study of Amlodipine 10 mg + Valsartan 160 mg film coated tablet of Actover. and NOVARTIS. in 24 healthy male under fasting.

Settings and conduct

In each period, volunteers will receive a single dose of the treatment in the Farabi Clinic (Eslamshahr, Tehran). 2 dosing periods will be separated by a 7-day washout period.

Participants/Inclusion and exclusion criteria

Healthy subjects (male) between 20 – 45 years of age and Body Mass Index (BMI) within 15% of normal range according to the accepted normal values 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 known allergy to the products tested. Acute infection within one week preceding first study drug administration.

Intervention groups

Intervention group (test): Amlodipine 10 mg + Valsartan 160 mg film coated tablet, produced by Actover is the test product. In each period, 12 of 24 subjects will be given a single oral dose of this product.Intervention group (Reference): EXFORGE®Tablet, produced by Janssen 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: **IRCT20180620040164N20**
Registration date: **2022-02-08, 1400/11/19**
Registration timing: **prospective**

Last update: **2022-02-08, 1400/11/19**
Update count: **0**

Registration date

2022-02-08, 1400/11/19

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

info@tavaninstitute.ir

Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2022-02-25, 1400/12/06

Expected recruitment end date

2022-03-11, 1400/12/20

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Comparative bioequivalence study of Amlodipine 10 mg plus Valsartan 160 mg film coated tablet of ACTOVERCO and NOVARTIS in 24 healthy male under fasting

Public title

Bioequivalence study of Amlodipine 10 mg + Valsartan 160 mg film coated tablet in 24 healthy male under fasting conditions

Purpose

Treatment

Inclusion/Exclusion criteria

Inclusion criteria:

Healthy subjects (male) between 20 – 45 years of age and Body Mass Index (BMI) within 15% of normal range according to the accepted normal values 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:

Subjects with known allergy to the products tested. Acute infection within one week preceding first study drug administration. Hypotension (systolic blood pressure ≤100 mmHg or diastolic blood pressure ≤65 mmHg) or hypertension (systolic blood pressure ≥150mmHg or diastolic blood pressure ≥100 mmHg). Smoking more than 10 cigarettes per day and could not tolerate cigarette cessation during each clinical 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. History of alcohol or drug abuse. Heavy drinker of caffeine, grapefruit juice or caffeinated drinks or who are on special diet (such as vegetarians) or 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 **20 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 the BEAR statistical software (Release V2.7.7). Each volunteer will be randomly assigned to one of the 2 different sequence of treatments according to the order of entering the study which will be allocated after screening.

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

2022-01-25, 1400/11/05

Ethics committee reference number

IR.SBMU.PHARMACY.REC.1400.291

Health conditions studied

1

Description of health condition studied

Bioequivalence investigation of the generic Actover. Amlodipine 10 mg + Valsartan 160 mg film coated tablet with brand EXFORGE® NOVARTIS Tablet.

ICD-10 code

ICD-10 code description

Primary outcomes

1

Description

Peak Plasma Concentration (Cmax)

Timepoint

During 2 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
During 2 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: (test): Amlodipine 10 mg + Valsartan 160 mg film coated tablet, produced by Actover is the test product. In each period, 12 of 24 subjects will be given single oral dose of this product.
Category
Treatment - Drugs

2

Description
Intervention group:Amlodipine 10 mg + Valsartan 160 mg film coated tablet produced by NOVARTIS is the test product. In each period, 12 of 24 subjects will be given single oral dose of this product.
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, Sallor city
City
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Province
Tehran
Postal code
4635314588
Phone
+98 21 9253 5647
Email
mina.hasanabadi@yahoo.com

Sponsors / Funding sources

1

Sponsor
Name of organization / entity
Actover Pharmaceutical Co.
Full name of responsible person
Reza karimi mostofi
Street address
58 plaque, 8th St., Gisha
City
Tehran
Province
Tehran
Postal code
1446863914
Phone
+98 21 4162 7000
Email
info@actoverco.com
Grant name
Grant code / Reference number
Is the source of funding the same sponsor organization/entity?
Yes
Title of funding source
Actover 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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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
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