

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 (C_{max})

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

Tehran

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

Street address

Sharif innovation station, North Habibollah, Hosseini
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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

Contact

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Tavan Institute

Full name of responsible person

Ali Aghaei

Position

Master

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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