Clinical Trial Protocol
Iranian Registry of Clinical Trials

04 Jul 2026

Comparative bioequivalence study of Aprepitant 125 mg capsule of ACTOVERCO and MERCK Inc. in 24 healthy male under fasting conditions

Protocol summary

Study aim
This study will be performed to compare the pharmacokinetics and invivo parameters of Aprepitant 125 mg formulation as a test product with EMEND® tablet formulation as a reference product and to evaluate the biocompatibility of these two formulations.

Design
Randomized, single-dose, crossover comparative bioequivalence study of Aprepitant 125 mg capsule of Actover. and Merk. 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) 18.5 - 30 (inclusive); Subjects with no significant diseases or clinically significant abnormal findings during screening, medical history, clinical examination, and laboratory evaluations; Subjects with normal vital signs; Known hypersensitivity to Aprepitant or its analogs; Smoking more than ten cigarettes per day and could not tolerate cigarette cessation during each clinical period.

Intervention groups
Intervention group (test): Aprepitant 125 mg capsule, 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): EMEND® capsule, produced by MERCK 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: **IRCT20180620040164N10**
Registration date: **2021-10-01, 1400/07/09**
Registration timing: **prospective**

Last update: **2021-10-01, 1400/07/09**
Update count: **0**

Registration date
2021-10-01, 1400/07/09

Registrant information

Name
Behzad Montaha Sangari

Name of organization / entity
Noor research and educational institute (Tavan)

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Iran (Islamic Republic of)

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Recruitment status
Recruitment complete

Funding source

Expected recruitment start date
2021-10-09, 1400/07/17

Expected recruitment end date
2021-10-23, 1400/08/01

Actual recruitment start date
empty

Actual recruitment end date
empty

Trial completion date
empty

Scientific title
Comparative bioequivalence study of Aprepitant 125 mg capsule of ACTOVERCO and MERCK Inc. in 24 healthy

male under fasting conditions

Public title
Bioequivalence study of Aprepitant 125 mg capsule 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 average 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 the patient consent form.
Exclusion criteria:
Subject has a history of mentally or legally incapacitated, significant emotional problems at the time of the study, a history of major psychiatric disorders, clinically significant disease history, cardiac or vascular disorder, asthma or another pulmonary disease, major gastrointestinal abnormalities/peptic ulceration, hepatic or hepatobiliary, neurologic, endocrine, hematologic, renal disease, major genitourinary disease. Known hypersensitivity to Aprepitant or its analogs. Smoking more than 10 cigarettes per day and could not tolerate cigarette cessation during each clinical period. Subjects who have 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 the study period. History of alcohol or drug abuse within 2 years before the start of the study. Heavy drinker of caffeine, grapefruit juice, or caffeinated drinks or who are on a 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: **26**
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
2021-04-27, 1400/02/07
Ethics committee reference number
IR.SBMU.PHARMACY.REC.1400.020

Health conditions studied

1

Description of health condition studied
Bioequivalence investigation of the generic Actover.Aprepitant 125 mg capsule with brand EMEND® Merk capsule.
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): Aprepitant 125 mg capsule, 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: Aprepitant 125 mg capsule, produced by Merk 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
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Email
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Sponsors / Funding sources

1

Sponsor
Name of organization / entity
ACtover Pharmaceutical Co.
Full name of responsible person
Nahaleh Naraghi
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58 plaque, 8th St., Gisha
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1446863914
Phone
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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
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Other areas of specialty/work
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Person responsible for updating data

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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
It's not specified yet.
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