Clinical Trial Protocol
Iranian Registry of Clinical Trials

03 Jul 2026

Comparative bioequivalence study of Gabapentin 300 mg capsule of Actoverco and PFIZER PHARMA PFE GmbH

Protocol summary

Study aim
This study will be performed to compare the pharmacokinetics and invivo parameters of Gabapentin 300 mg capsules formulation as a test product with NEURONTIN ® 300 mg capsule formulation as a reference product and to evaluate the biocompatibility of these two formulations.

Design
Randomized, single-dose, crossover comparative bioequivalence study of Gabapentin 300 mg capsule of Actoverco and PFIZER PHARMA PFE GmbH 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 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 ECG and vital signs. Known hypersensitivity or idiosyncratic reaction to gabapentin or inactive ingredients. Subjects with a known history of allergic reaction or drug intolerance. History of cardiovascular, renal, hepatic, metabolic, gastrointestinal, neurologic, endocrine, hematopoietic, psychiatric or organic condition.

Intervention groups
Intervention group (test): Gabapentin 300 mg capsule, produced by Actoverco is the test product. In each period, 12 of 24 subjects will be given a single oral dose of this product. Intervention group (Reference): NEURONTIN ® 300 mg capsule, produced by PFIZER PHARMA PFE GmbH 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: **IRCT20180620040164N24**
Registration date: **2022-04-13, 1401/01/24**
Registration timing: **retrospective**

Last update: **2022-04-13, 1401/01/24**
Update count: **0**

Registration date
2022-04-13, 1401/01/24

Registrant information

Name
Behzad Montaha Sangari

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

Country
Iran (Islamic Republic of)

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+98 21 6600 7026

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Recruitment status
Recruitment complete

Funding source

Expected recruitment start date
2020-01-04, 1398/10/14

Expected recruitment end date
2020-01-25, 1398/11/05

Actual recruitment start date
empty

Actual recruitment end date
empty
Trial completion date
empty

Scientific title
Comparative bioequivalence study of Gabapentin 300 mg capsule of Actoverco and PFIZER PHARMA PFE GmbH

Public title
Bioequivalence study of Gabapentin 300 mg capsules in 24 healthy male under fasting conditions
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 ECG and vital signs. Subjects who agree with patient consent form. Non-smoking at least for 10 hours before study.
Exclusion criteria:
Known hypersensitivity or idiosyncratic reaction to gabapentin or inactive ingredients. Subjects with a known history of allergic reaction or drug intolerance. History of cardiovascular, renal, hepatic, metabolic, gastrointestinal, neurologic, endocrine, hematopoietic, psychiatric or organic condition. 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. Subjects who have a history of alcohol or substance abuse within the last year. Heavy drinker of alcohol, 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 450 ml blood within 60 days prior to the start of the study.
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's number (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 of Shahid Beheshti University of Medical Sciences
Street address
Niayesh Highway, Valiasr Ave, Tehran, Iran
City
Tehran
Province
Tehran
Postal code
1996835113
Approval date
2020-02-03, 1398/11/14
Ethics committee reference number
IR.SBMU.PHAMACY.REC.1398.266

Health conditions studied

1

Description of health condition studied
Bioequivalence investigation of the generic Actoverco Gabapentin 300 mg capsule with brand NEURONTIN ® 300 mg capsule PFIZER PHARMA PFE GmbH.
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):Gabapentin 300 mg capsule, produced by Actoverco 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: Gabapentin 300 mg Capsule, produced by PFIZER is the refrence 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
روبروی شهرک سالور - نبش کوچه شمشاد - پلاک ۵۷
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Email
mina.hasanabadi@yahoo.com

Sponsors / Funding sources

1

Sponsor
Name of organization / entity
Actoverco Pharmaceutical Co.
Full name of responsible person
نهاله نراقی
Street address
58 plaque, 8th St., Gishaگیشا، خیابان هشتم، پلاک 58 شهر
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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?
No
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

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Seyed Mohsen Foroutan

Position
Principal investigator

Latest degree
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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)
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