Clinical Trial Protocol
Iranian Registry of Clinical Trials

07 Nov 2026

Comparative bioequivalence study of Gabapentin 300 mg Capsule of Dorsa Pharmaceutical Co. and PFIZER Inc. in 24 healthy male under fasting

Protocol summary

Study aim

This study will be performed to compare the pharmacokinetics and invivo parameters of Gabapentin 300 mg Capsule formulation as a test product with NEURONTIN® 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 of Dorsa Pharmaceutical Co. and PFIZER 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. Known hypersensitivity or idiosyncratic reaction to gabapentin or inactive ingredients. Subjects with a known history of allergic reaction or drug intolerance.

Intervention groups

Intervention group (test): Gabapentin 300 mg Cpsule, 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 (Reference): NEURONTIN® capsule, produced by PFIZER 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: **IRCT20180620040164N16**
Registration date: **2021-12-13, 1400/09/22**
Registration timing: **prospective**

Last update: **2021-12-13, 1400/09/22**
Update count: **0**

Registration date

2021-12-13, 1400/09/22

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

2022-01-07, 1400/10/17

Expected recruitment end date

2022-01-14, 1400/10/24

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 Dorsa Pharmaceutical Co. and PFIZER Inc. in 24 healthy male under fasting

Public title
Bioequivalence study of Gabapentin 300 mg Capsule 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: **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
2021-08-10, 1400/05/19

Ethics committee reference number
1400.117

Health conditions studied

1

Description of health condition studied
Bioequivalence investigation of the generic Dorsa Pharmaceutical Co. Gabapentin 300 mg Capsule with brand NEURONTIN® PFIZER 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: Intervention group: (test):Gabpentin 300 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.
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
No. 57, Shemshad alley, Sallor city
City
Tehran
Province
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Postal code
4635314588
Phone
+98 21 9253 5647
Email
mina.hasanabadi@yahoo.com

Sponsors / Funding sources

1

Sponsor
Name of organization / entity
Dorsa Pharmaceutical Co.
Full name of responsible person
Amir esmael Saghafinia
Street address
Teimori-Shahid Salehi Blv-Fanavari Tarash Tower-8th floor
City
Tehran
Province
Tehran
Postal code
۱۴۵۹۹۶۵۲۰۴
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
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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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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Master

Latest degree
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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