

Clinical Trial Protocol

Iranian Registry of Clinical Trials

03 Jul 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 Capsule, 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 (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: 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 reference 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

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

۱۴۵۹۹۶۵۲-۴

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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Sharif innovation station, North Habibollah, Hosseini Squ., Teymoury St., Tarasht

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Email

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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

Name of organization / entity

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Full name of responsible person

Ali Aghaei

Position

Master

Latest degree

Master

Other areas of specialty/work

Pharmacy

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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