

# 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/m<sup>2</sup>. 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/m<sup>2</sup>. 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<sub>max</sub>)

#### 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

##### Street address

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

##### City

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##### Province

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##### Postal code

1459926609

##### Phone

+98 21 6600 4027

##### Email

info@tavaninstitute.ir

## 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

**Street address**

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**Person responsible for updating data**

**Contact**

**Name of organization / entity**

Tavan Institute

**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