Clinical Trial Protocol
Iranian Registry of Clinical Trials

14 Jun 2026

Comparative bioequivalence study of single oral dose of Gabapentin 300 mg capsules produced by Daana pharmaceutical Co versus NEURONTIN® (Pfizer company) in 24 healthy males under fasting conditions

Protocol summary

Study aim

To demonstrate bioequivalence of single dose test formulation of Daana Gabapentin 300 mg capsules versus NEURONTIN®(Pfizer Co.)

Design

Single dose, randomized and crossover bioequivalence study of Gabapentin 300 mg capsules by Daana Co. with NEURONTIN® (Pfizer Co.) in 24 healthy male in two groups under fasting condition.Data will be analyzed with Exel and SPSS software.

Settings and conduct

Study place: Drug Applied Research Center affiliated to Tabriz University of Medical Science. Place for Blood and plasma sample analysis: Imam Reza Medical Research and Trainning Hospital. 24 healthy male volunteers will received each of two test or reference Gabapentin 300 mg capsules in random sequence according to the randomization schedule. The interval between receiving the medicine (washout period) is 7 days. Blood samples of volunteers at 0 (before dosing), 0.5، 1، 1.5، 2، 2.5، 3، 4، 6، 8، 10، 12، 24 and 48 hour after dosing will be collected.

Participants/Inclusion and exclusion criteria

The weight limit for each volunteer is between 60 and 100 kg. They must be healthy in terms of liver, kidney, respiratory system, mental and other general health characteristics that will be assessed. Exclusion criteria: Known hypersensitivity or idiosyncratic reaction to Gabapentin or any ingredients. Subjects with BP ≤ 90/60 mm/Hg or BP ≥ 140/90 mm/Hg. Regular smoker who smokes more than ten cigarettes daily.

Intervention groups

Intervention group 1: In this group, volunteers are given a single oral dose of Gabapentin 300 mg capsules by Daana Co. Intervention group 2: In this group, volunteers are given a single oral dose of NEURONTIN® capsules of Pfizer company. After the washout period, the volunteers are placed in the opposite group. In fact, every single volunteers is used as control for himself.

Main outcome variables

Peak Plasma Concentration (Cmax); Area under the concentration-time curve (AUC).

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20200407046981N17**
Registration date: **2021-09-29, 1400/07/07**
Registration timing: **prospective**

Last update: **2021-09-29, 1400/07/07**
Update count: **0**

Registration date

2021-09-29, 1400/07/07

Registrant information

Name

Fatima Molavi

Name of organization / entity

Country

Iran (Islamic Republic of)

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Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2021-10-07, 1400/07/15

Expected recruitment end date

2022-01-05, 1400/10/15

Actual recruitment start date
empty
Actual recruitment end date
empty
Trial completion date
empty

Scientific title
Comparative bioequivalence study of single oral dose of Gabapentin 300 mg capsules produced by Daana pharmaceutical Co versus NEURONTIN® (Pfizer company) in 24 healthy males under fasting conditions

Public title
Study of absorption and elimination rate of Gabapentin 300 mg capsules in comparison with standard capsules of Gabapentin (NEURONTIN®).
Purpose
Treatment
Inclusion/Exclusion criteria
Inclusion criteria:
The weight limit for each volunteer is between 60 and 100 kg. All volunteers must be non-smokers. They must be healthy in terms of liver, kidney, respiratory system, mental and other general health characteristics that will be assessed.
Exclusion criteria:
Known hypersensitivity or idiosyncratic reaction to Gabapentin or any ingredients. Subjects with BP ≤ 90/60 mm/Hg or BP ≥ 140/90 mm/Hg. Regular smoker who smokes more than ten cigarettes daily. Taking any medicine during two week before dosing.
Age
From **18 years** old to **60 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
Individuals will be recruited voluntarily through advertising. A table of random numbers from 1 to 24 is created and 24 volunteers are randomly assigned to two sequences by lottery method. In the first period, the candidates in two groups with numbers 1-12 and numbers 13-24 will receive reference and test drugs, respectively, and in the second period, vice versa.
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 Tabriz University of Medical Science
Street address
Third floor, central building No. 2, Golgasht street, Tabriz University of Medical Science, Tabriz, Iran
City
Tabriz
Province
East Azarbaijan
Postal code
5166614766
Approval date
2021-03-01, 1399/12/11
Ethics committee reference number
IR.TBZMED.REC.1399.1148

Health conditions studied

1

Description of health condition studied
In this study, the disease is not examined. The subject of the study is the bioequivalence study of the Gabapentin 300 mg of test and reference in healthy volunteers.
ICD-10 code
ICD-10 code description

Primary outcomes

1

Description
Peak Plasma Concentration (Cmax)
Timepoint
At 0 (before intervention), 0.5، 1، 1.5، 2، 2.5، 3، 4، 6، 8، 10، 12، 24 and 48 hour after dosing
Method of measurement
High-performance liquid chromatography—mass spectrometry (HPLC-MS)

Secondary outcomes

1

Description
AUC (Area Under the Concentration-Time Curve)
Timepoint
At 0 (before dosing), 0.5، 1، 1.5، 2، 2.5، 3، 4، 6، 8، 10، 12، 24 and 48 hour after dosing
Method of measurement
Using non-compartmental model of Win-Nonlin Professional software version 3.2.A (Pharsight

Corporation, USA) or SPSS

Intervention groups

1

Description
Intervention group 1: In this group, volunteers are given a single oral dose of Gabapentin 300 mg capsules, produced by Daana pharmaceutical Co. (Domestic). After the washout period, the volunteers are placed in the Intervention group 2. In fact, every single volunteers is used as control for himself.
Category
Treatment - Drugs

2

Description
Intervention group 2: In this group, volunteers are given a single oral dose of Gabapentin 300 mg capsules, produced by Pfizer pharmaceutical Co. (Brand). After the washout period, the volunteers are placed in the Intervention group 1. In fact, every single volunteers is used as control for himself.
Category
Treatment - Drugs

Recruitment centers

1

Recruitment center
Name of recruitment center
Drug Applied Research Center
Full name of responsible person
Dr Hamed Hamishehkar
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Drug Applied Research Center, In front of Shahid Madani Hospital, Daneshghah Blvd, Tabriz, Iran
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hamishehkar.hamed@gmail.com
Web page address
https://darc.tbzmed.ac.ir/

Sponsors / Funding sources

1

Sponsor
Name of organization / entity
Daana pharmaceutical company
Full name of responsible person
Ahmad Kharazi
Street address
East Azerbaijan Province, Basmenj, Tehran - Tabriz Fwy
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Province
East Azarbaijan
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5495151673
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Email
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Grant name
Grant code / Reference number
Is the source of funding the same sponsor organization/entity?
Yes
Title of funding source
Daana pharmaceutical company
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
Tabriz University of Medical Sciences
Full name of responsible person
Hamed Hamishehkar
Position
Professor
Latest degree
Ph.D.
Other areas of specialty/work
Pharmaceutics
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Person responsible for scientific inquiries

Contact

Name of organization / entity
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Full name of responsible person
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Position
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Latest degree
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Person responsible for updating data

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Position
PhD student of Pharmaceutics

Latest degree
Medical doctor

Other areas of specialty/work
Pharmaceutics

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Sharing plan

Deidentified Individual Participant Data Set (IPD)
Undecided - It is not yet known if there will be a plan to make this available

Study Protocol
Undecided - It is not yet known if there will be a plan to make this available

Statistical Analysis Plan
Undecided - It is not yet known if there will be 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