Clinical Trial Protocol
Iranian Registry of Clinical Trials

17 Sep 2026

A randomized, open label, two treatments, two periods, two sequence, single dose, crossover, bioequivalence study of Gabapentin 300mg capsule of Alborzdarou Pharm Co., IRAN in comparison of Neurontin 300mg capsule of PFIZER in 24 healthy adult subjects under fasting condition

Protocol summary

Study aim

- To characterize the rate and extent of bioavailability of test product in comparison of reference product after single dose administration in healthy, adult subjects under fasting conditions. - To assess the bioequivalence of test formulation (Gabapentin 300mg capsule of Alborzdarou Pharm Co.) with reference product (Neurontin 300mg capsule of PFIZER) by means of AUC0-24 and Cmax . - Monitor the safety of the subjects participating in the study and tolerability of the test product in comparison with reference considering adverse events

Design

A randomized, open label, two treatments, two periods, two sequence, single dose, crossover, bioequivalence study of Gabapentin 300mg capsule of Alborzdarou Pharm Co., IRAN and Neurontin 300mg capsule of PFIZER in 24 healthy adult subjects under fasting condition

Settings and conduct

1- 24 healthy subjects enroll in this project. Volunteers provide written informed consent. They find to be healthy based on the history and physical examinations as well as clinical laboratory profiles. 2- A single dose of 300 mg gabapentin capsule will administer, in each study period. 3-The Blood samples collect by direct vein punctures before and at 0 (before dosing), 1.0, 1.5, 2.0, 2.5, 3.0, 3.5, 4.0, 5.0, 6.0, 8.0, 10.0 & 24.0 hours' post-dose. 4- The treatment phases separate by a washout period of at least 7 days. 5- Plasma samples will transfer to analytical Lab. to measuring gabapentin in the plasma.

Participants/Inclusion and exclusion criteria

- Aged between 20 - 50 years - Body weight between 50 – 100 kg - Having good health on the basis of medical history and physical & clinical examination. - Understand the procedures and give written informed consent

Intervention groups

- Gabapentin 300mg capsule of Alborzdarou Pharm Co. - Neurontin 300mg capsule of PFIZER

Main outcome variables

Plasma concentration of gabapentin

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20190706044111N6**
Registration date: **2019-09-06, 1398/06/15**
Registration timing: **prospective**

Last update: **2019-09-06, 1398/06/15**
Update count: **0**

Registration date

2019-09-06, 1398/06/15

Registrant information

Name
Ladan Tayebi

Name of organization / entity
Pars Biopharmacy Research Co.

Country
Iran (Islamic Republic of)

Phone
+98 21 8895 6061

Email address
l.tayebi@parsbiopharmacy.com

Recruitment status

Recruitment complete

Funding source

Expected recruitment start date
2019-11-22, 1398/09/01
Expected recruitment end date
2020-09-21, 1399/06/31
Actual recruitment start date
empty
Actual recruitment end date
empty
Trial completion date
empty

Scientific title
A randomized, open label, two treatments, two periods, two sequence, single dose, crossover, bioequivalence study of Gabapentin 300mg capsule of Alborzdarou Pharm Co., IRAN in comparison of Neurontin 300mg capsule of PFIZER in 24 healthy adult subjects under fasting condition

Public title
Bioequivalence study of Gabapentin 300mg capsule of Alborzdarou Pharm Co.,
Purpose
Other
Inclusion/Exclusion criteria
Inclusion criteria:
Aged between 20 - 50 years Body weight between 50 – 100 kg Having good health on the basis of medical history and physical & clinical examination Understand the procedures and give written informed consent
Exclusion criteria:
Age
From **20 years** old to **50 years** old
Gender
Both

Phase
Bioequivalence
Groups that have been masked
No information
Sample size
Target sample size: **24**
More than 1 sample in each individual
Number of samples in each individual: **2**
Each volunteer, 2 times take medicine in the study. One time test product and the other time reference product with at least one week wash-out period.
Randomization (investigator's opinion)
Not randomized
Randomization description
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 Zahedan University of medical Sciences
Street address
Dr. Hessabi square Zahedan University of Medical Sciences
City
Zahedan
Province
Sistan-va-Balouchestan
Postal code
9816743463
Approval date
2019-07-28, 1398/05/06
Ethics committee reference number
IR.ZAUMS.REC.1398.183

Health conditions studied

1

Description of health condition studied
Neuralgia and neuropathic disorders
ICD-10 code
ICD-10 code description

Primary outcomes

1

Description
Plasma concentration of gabapentin
Timepoint
0 (before dosing), 1.0, 1.5, 2.0, 2.5, 3.0, 3.5, 4.0, 5.0, 6.0, 8.0, 10.0 & 24.0 hr. after dosing
Method of measurement
HPLC

Secondary outcomes

empty

Intervention groups

1

Description
Intervention group: Gabapentin 300mg capsule of Alborzdarou Pharm Co.
Category
Other

2

Description
Control group: Neurontin 300mg capsule of PFIZER
Category
Other

Recruitment centers

1

Recruitment center
Name of recruitment center
Core Research Lab. of ZAUMS
Full name of responsible person
Gholamreza Komeili
Street address
Emam Ali Hospital, Salamat Blv., Khalij-e-Fars Highway
City
Zahedan
Province
Sistan-va-Balouchestan
Postal code
9816743111
Phone
+98 54 3329 5664
Fax
+98 54 3329 5665
Email
crl@zaums.ac.ir
Web page address
http://crl.zaums.ac.ir/

Sponsors / Funding sources

1

Sponsor
Name of organization / entity
Alborzdarou Pharm. Co.
Full name of responsible person
Ali Mortazavi
Street address
8th Hekmat street, Alborz Industrial City, Ghazvin
City
Ghazvin
Province
Qazvin
Postal code
3431957693
Phone
+98 28 3222 1001
Fax
+98 28 3222 1001
Email
info@alborzdarouco.com
Web page address
http://www.alborzdarouco.com
Grant name
Grant code / Reference number
Is the source of funding the same sponsor organization/entity?
Yes
Title of funding source
Alborzdarou Pharm. 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
Pars Biopharmacy Research Co.
Full name of responsible person
Ladan Tayebi
Position
Managing Director
Latest degree
Medical doctor
Other areas of specialty/work
Medical Pharmacy
Street address
1st floor, Saeidi Dd end, Felestin Ave.
City
Tehran
Province
Tehran
Postal code
1416673971
Phone
+98 21 8895 6061
Fax
+98 21 8896 9958
Email
l.tayebi@parsbiopharmacy.com

Person responsible for scientific inquiries

Contact
Name of organization / entity
Pars Biopharmacy Research Co.
Full name of responsible person
Ladan Tayebi
Position
Managing Director
Latest degree
Medical doctor
Other areas of specialty/work
Medical Pharmacy
Street address
1st floor, Saeidi Dd end, Felestin Ave.
City
Tehran

Province
Tehran
Postal code
کدپستی: 1416673971
Phone
+98 21 8895 6061
Fax
+98 21 8896 9958
Email
l.tayebi@parsbiopharmacy.com
Web page address

Person responsible for updating data

Contact
Name of organization / entity
Pars Biopharmacy Research Co.
Full name of responsible person
Ladan Tayebi
Position
Managing Director
Latest degree
Medical doctor
Other areas of specialty/work
Medical Pharmacy
Street address
1st floor, Saeidi Dd end, Felestin Ave.
City
Tehran
Province
Tehran
Postal code
کدپستی: 1416673971
Phone
+98 21 8895 6061
Fax
+98 21 8896 9958
Email
l.tayebi@parsbiopharmacy.com
Web page address

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
Undecided - It is not yet known if there will be a plan to make this available
Clinical Study Report
Undecided - It is not yet known if there will be a plan to make this available
Analytic Code
Undecided - It is not yet known if there will be a plan to make this available
Data Dictionary
Undecided - It is not yet known if there will be a plan to make this available