

Clinical Trial Protocol

Iranian Registry of Clinical Trials

01 Jul 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 C_{max} . - 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

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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

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Province

Qazvin

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Phone

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Fax

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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

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Person responsible for scientific inquiries

Contact

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City

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Province

Tehran

Postal code**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