Clinical Trial Protocol
Iranian Registry of Clinical Trials

16 Sep 2026

Bioequivalency study of two different gabapentin formulations

Protocol summary

Summary

Objectives: Today, biological equivalence studies what in terms of acquisitions and the survival of invitro quality of drug product and how statistical equality rate and the amount of bioavailability with the world's most reliable pharmaceutical product market (reference) are remarkable importance In our country, in recent decades also seeks to establish a new system of medical management, particular attention to the issue of biological equivalence. So different groups of researchers at medicinal universities and the private sector carry out tests of bioequivalency for market products. This study as part of the domestically program of bio-equivalence tests, was carried out to assess the equivalence of gabapentin 300 mg capsules produced in Sobhan Daru company compare to a reference product. Design: plan consists of two independent parts, invitro tests, with the aim of evaluating the quality of the test and reference products based on pharmacopoeia standards and after approval, invivo studies on 24 volunteer with the aim of providing the rate and amount of bioavailability. Inclusion criteria: 24 healthy male and female volunteers, average age of 18 to 45 years, based on laboratory safety tests, no history of diseases affecting drug pharmacokinetic processes; lack of any chronic or acute medication at least 1 week before the start of the study Interventions: single-dose of two formulations containing 300 mg gabapentin (Sobhan daru and reference) administrate to the volunteers in an open, randomized, crossover, 2 periods x 2 sequences, with a minimum washout period of 7 days. Blood sampling was taken at the designated times, and drug was extracted by liquid extraction method and analyzed by HPLC instrument and UV detection. Main outcome variables: From plasma concentration- time curves and pharmacokinetic models, all drug kinetic parameters in both formulations were calculated and biological equivalency of two formulations was evaluated.

General information

Acronym

IRCT registration information

IRCT registration number: **IRCT201511058022N3**
Registration date: **2016-08-10, 1395/05/20**
Registration timing: **retrospective**

Last update:
Update count: **0**

Registration date

2016-08-10, 1395/05/20

Registrant information

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Name of organization / entity
Hamadan University of Medical Sciences, Pharmacy school
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Recruitment status

Recruitment complete

Funding source

Sobhan Daru pharmaceutical company

Expected recruitment start date

2015-11-20, 1394/08/29

Expected recruitment end date

2015-11-27, 1394/09/06

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title
Bioequivalency study of two different gabapentin formulations

Public title
Comparative study on the bioequivalence of two different gabapentin 300mg formulations (Sobhan daru & reference) in 24 iranian volunteers
Purpose
Health service research
Inclusion/Exclusion criteria
Inclusion criteria: 24 healthy male and female volunteers will participate in this study. Aged 18 to 45 years, based on laboratory safety tests, no history of diseases affecting drug pharmacokinetic processes; lack of any chronic or acute medication at least 1 week before the start of the study, adherence to the criteria on the basis of moral obligation and signed an informed consent; actual weight (TBW) in the range of 20% IBW Exclusion criteria: Age outside the range mentioned; acute or chronic smoking or alcohol, failure to obtain any of the above health tests, medication two weeks before the experiment
Age
From **20 years** old to **45 years** old
Gender
Both

Phase
Bioequivalence
Groups that have been masked
No information
Sample size
Target sample size: **24**
Randomization (investigator's opinion)
N/A
Randomization description
Blinding (investigator's opinion)
Double blinded
Blinding description
Placebo
Not used
Assignment
Crossover
Other design features

Secondary Ids

1

Registry name
--
Secondary trial Id
--
Registration date
empty

Ethics committees

1

Ethics committee
Name of ethics committee
Ethics committees, Kermanshah University of Medical Sciences
Street address
Kermanshah University of Medical Sciences
City
Kermanshah
Postal code
Approval date
2015-07-22, 1394/04/31
Ethics committee reference number
KUMS.REC.1394.431

Health conditions studied

1

Description of health condition studied
Health and normal volunteers
ICD-10 code
--
ICD-10 code description
--

Primary outcomes

1

Description
Drug plasma concentration
Timepoint
hour
Method of measurement
blood sampling

Secondary outcomes

1

Description
Pharmacokinetic parameters
Timepoint
after intervention
Method of measurement
theoretical and pahrmacokinetic equations

Intervention groups

1

Description
single dose, Neurontin 300 mg tablet, Pfizer Pharma Gmbh, as reference product
Category
Treatment - Drugs

2

Description
Single dose, Gabax 300 mg, Sobhan daru company, as test product

Category
Treatment - Drugs

Recruitment centers

1

Recruitment center
Name of recruitment center
Faculty of Pharmacy, Kermanshah University of Medical Sciences
Full name of responsible person
Masoud Seidi
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Pharmaceutics lab, Faculty of Pharmacyl, Parastar Blvd., Daneshgah Street, Kermanshah, Iran
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Sponsors / Funding sources

1

Sponsor
Name of organization / entity
Sobhan Daru pharmaceutical company
Full name of responsible person
Dr. Akbar Borandegi
Street address
Sobhan Daru pharmaceutical company, Rasht Industrial City, Rasht, Iran
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Rasht
Grant name
Grant code / Reference number
Is the source of funding the same sponsor organization/entity?
Yes
Title of funding source
Sobhan Daru pharmaceutical company
Proportion provided by this source
Public or private sector
empty
Domestic or foreign origin
empty
Category of foreign source of funding
empty
Country of origin
Type of organization providing the funding
empty

2

Sponsor
Name of organization / entity
Vice chancellor for research, Kermanshah University of Medical Sciences
Full name of responsible person
Dr. Behrouz Hamzeh
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Vice chancellor for research, Kermanshah University of Medical Science, Shaheed Behshtee Blvd., Kermanshah, Iran
City
Kermanshah
Grant name
Grant code / Reference number
Is the source of funding the same sponsor organization/entity?
Yes
Title of funding source
Vice chancellor for research, Kermanshah University of Medical Sciences
Proportion provided by this source
Public or private sector
empty
Domestic or foreign origin
empty
Category of foreign source of funding
empty
Country of origin
Type of organization providing the funding
empty

Person responsible for general inquiries

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Sharing plan

Deidentified Individual Participant Data Set (IPD)
empty
Study Protocol
empty
Statistical Analysis Plan
empty
Informed Consent Form
empty
Clinical Study Report
empty
Analytic Code
empty
Data Dictionary
empty