

# Clinical Trial Protocol

## Iranian Registry of Clinical Trials

03 Jul 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

##### Name

Katayoun Derakhshandeh

##### Name of organization / entity

Hamadan University of Medical Sciences, Pharmacy school

##### Country

Iran (Islamic Republic of)

##### Phone

+98 81 3838 1590

##### Email address

kderakhshandeh@kums.ac.ir

##### 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

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#### 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

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#### ICD-10 code description

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## 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 pharmacokinetic 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  
**Street address**  
Pharmaceutics lab, Faculty of Pharmacy, Parastar Blvd., Daneshgah Street, Kermanshah, Iran  
**City**  
Kermanshah

## 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  
**City**  
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  
**Street address**  
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

### Contact

**Name of organization / entity**  
Kermanshah University of Medical Sciences  
**Full name of responsible person**  
Gholamreza Bahrami  
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## Person responsible for scientific inquiries

### Contact

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## Person responsible for updating data

### Contact

**Name of organization / entity**

Hamadan University of Medical Sciences

**Full name of responsible person**

Katayoun Derakhshandeh

**Position**

Faculty President

**Other areas of specialty/work**

**Street address**

Faculty of Pharmacy , Hamadan University of Medical Sciences, Shaheed Fahmideh Blvd., In front of Mardom Park, Hamadan, Iran

**City**

Hamadan

## 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*