Clinical Trial Protocol
Iranian Registry of Clinical Trials

06 Jun 2026

Comparative bioequivalence study of Levodopa/Benserazide 200/50 mg tablet of Cosar pharmaceutical Co. and Madopar 250 mg tablet of Roche as reference in 24 healthy male under fasting.

Protocol summary

Study aim

This study will be performed to compare the pharmacokinetics and invivo parameters of Levodopa/Benserazide 200/50 mg tablet formulation as a test product with Madopar 250 mg formulation as a reference product and to evaluate the bioequivalence of these two formulations.

Design

Non blinded, randomized, crossover in vivo bioequivalence study in 24 healthy male under fasting condition.

Settings and conduct

In each period, volunteers will receive a single dose intervention (1 or 2) in the Farabi Clinic (Eslamshahr, Tehran).17 blood samples were collected during 72 hours post intervention. A 7-day washout interval separated to study periods.

Participants/Inclusion and exclusion criteria

Healthy subjects (male) between 20 – 45 years of age and Body Mass Index (BMI) within 15% of normal range between 18.5 - 30 kg/m2. Subjects with no significant diseases or clinically significant abnormal findings during screening, medical history, clinical examination and laboratory evaluations. Subjects with known allergy to the products tested. History of cardiovascular, hepatic, renal, psychiatric, neurologic, hematologic, or metabolic disease.

Intervention groups

Intervention group 1: Levodopa/Benserazide 200/50 mg tablet , produced by Cosar pharmaceutical Co. is the test product. In each period, 12 of 24 subjects will be given a single oral dose of this product. Intervention group 2: Madopar 250 mg tablet , produced by Roche is the reference product. In each period, 12 of 24 subjects will be given a single oral dose of this product.

Main outcome variables

Peak Plasma Concentration

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20180620040164N30**
Registration date: **2022-06-13, 1401/03/23**
Registration timing: **prospective**

Last update: **2022-06-13, 1401/03/23**
Update count: **0**

Registration date

2022-06-13, 1401/03/23

Registrant information

Name
Behzad Montaha Sangari
Name of organization / entity
Noor research and educational institute (Tavan)
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Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2022-06-22, 1401/04/01

Expected recruitment end date

2022-07-05, 1401/04/14

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title
Comparative bioequivalence study of Levodopa/Benserazide 200/50 mg tablet of Cosar pharmaceutical Co. and Madopar 250 mg tablet of Roche as reference in 24 healthy male under fasting.

Public title
Comparative in vivo evaluation of 2 Levodopa/Benserazide 200/50 mg Tablet formulations.

Purpose
Treatment

Inclusion/Exclusion criteria

Inclusion criteria:
Healthy subjects (male) between 20 – 45 years of age and Body Mass Index (BMI) within 15% of normal range between 18.5 - 30 kg/m2. Subjects with no significant diseases or clinically significant abnormal findings during screening, medical history, clinical examination and laboratory evaluations. Subjects that have normal vital signs. Subjects who agree with patient consent form.

Exclusion criteria:
Subjects with known allergy to the products tested. History of cardiovascular, hepatic, renal, psychiatric, neurologic, hematologic, or metabolic disease Smoking more than 10 cigarettes per day and could not tolerate cigarette cessation during each clinical period. Subjects who has used any drug including prescription or Over-The-Counter (OTC) drugs within 14 days prior to the start of the study and might need drug intake during study period. History of alcohol or drug abuse within 2 years before the start of the study. Heavy drinker of caffeine, grapefruit juice or caffeinated drinks or who are on special diet (such as vegetarians) or do exertional physical activity. A history of difficulty with donating blood or donation of more than 500 ml blood within 7 days prior to the start of the study.

Age
From **20 years** old to **45 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
The randomization schedule will be generated with https://www.sealedenvelope.com/simple-randomiser/v1/lists. A 2*2 block randomization list is created. We have 12 blocks and within each two volunteer's number (allocated after screening) for all 24 volunteers. According to this list, a treatment sequence of Test/Reference or Reference/Test will be given to each volunteer.

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 School of Pharmacy and Nursing & Midwifery- Shahid Beheshti University of Medica

Street address
Niayesh Highway, Valiasr Ave, Tehran, Iran

City
Tehran

Province
Tehran

Postal code
1996835113

Approval date
2021-07-20, 1400/04/29

Ethics committee reference number
IR.SBMU.PHARMACY.REC.1400.096

Health conditions studied

1

Description of health condition studied
parkinson's disease

ICD-10 code
G20

ICD-10 code description
Parkinson's disease

Primary outcomes

1

Description
Peak Plasma Concentration (Cmax)

Timepoint
17 blood samples will be withdrawn pre-dose and at 0.5, 1, 1.5, 2, 2.5, 3, 3.5, 4, 5, 6, 8, 9, 10, 12, 24, 48 and 72 hours after intervention.

Method of measurement
Using non-compartmental model of Win-Nonlin Professional software version 3.2.A (Pharsight Corporation, USA)

Secondary outcomes

1

Description
AUC (Area Under the Concentration-Time Curve)
Timepoint
17 blood samples will be withdrawn pre-dose and at 0.5, 1, 1.5, 2, 2.5, 3, 3.5, 4, 5, 6, 8, 9, 10, 12, 24, 48 and 72 hours after intervention.
Method of measurement
Using non-compartmental model of Win-Nonlin Professional software version 3.2.A (Pharsight Corporation, USA)

Intervention groups

1

Description
Intervention group 1: Levodopa/Benserazide 200/50 mg tablet , produced by Cosar pharmaceutical Co. is the test product. In each period, 12 of 24 subjects will be given single oral dose of this product. After 7-day wash-out period the intervention 2 will be given to these subjects.
Category
Treatment - Drugs

2

Description
Intervention group 2: Madopar 250 mg tablet, produced by Roche is the reference product. In each period, 12 of 24 subjects will be given single oral dose of this product. After 7-day wash-out period the intervention 1 will be given to these subjects.
Category
Treatment - Drugs

Recruitment centers

1

Recruitment center
Name of recruitment center
Hakim Farabi Clinic
Full name of responsible person
Ebrahim Siahpoosh
Street address
No. 57, Shemshad alley, in front of Sallor town.
City
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4635314588
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Sponsors / Funding sources

1

Sponsor
Name of organization / entity
Cosar pharmaceutical Co.
Full name of responsible person
Dr. Mohammad Soltani
Street address
Darougar street, 17km Old Way Karaj-Tehran.
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Province
Tehran
Postal code
1415519871
Phone
+98 21 4492 1074
Email
info@cosarpharm.com
Grant name
Grant code / Reference number
Is the source of funding the same sponsor organization/entity?
Yes
Title of funding source
Cosar pharmaceutical 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
Noor Research & Development Institute
Full name of responsible person
Ali Aghaei
Position
Master
Latest degree
Master
Other areas of specialty/work
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Person responsible for updating data

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Sharing plan

Deidentified Individual Participant Data Set (IPD)
No - There is not a plan to make this available

Justification/reason for indecision/not sharing IPD
It's undetermind yet.

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

Statistical Analysis Plan
No - There is not 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