Clinical Trial Protocol
Iranian Registry of Clinical Trials

13 Jun 2026

In- Vivo Bioequivalence study of Levodopa/Carbidopa/Entecapone tablet 200/50/200mg Fanda Pharma (Staparkin 200/50/200mg) with brand drugs (Stalevo 200/50/200mg Novartis, Germany) in Iranian healthy volunteers.

Protocol summary

Study aim

In- Vivo Bioequivalence study of Levodopa/Carbidopa/Entecapone tablet 200/50/200mg Fanda Pharma (Staparkin 200/50/200mg) with brand drugs (Stalevo 200/50/200mg Novartis, Germany) in Iranian healthy volunteers.

Design

Single dose, randomized, two sequences, two period crossover with a washout period.

Settings and conduct

This study will be conducted in two-way, cross-over and fasting, and on two sets of healthy volunteers. The study will be conducted in two periods of twenty-four hours.The interval between these two periods, which is called the wash-out time, is determined by the half-life of the drug plasma, which according to scientific sources should be at least 5 to 7 half-life of the drug in the case of the drug under study. The plan will take a week to clean up the drug, given the biological half-life of the drugs in the drug form.In the first round, candidates are divided into two groups, and the first group receives a test tablet and the second group receives a similar tablet. Blood samples will taken by the volunteer by the technician immediately after taking the drug, and the preparation steps of the samples, including plasma separation and drug extraction, are performed to analyze the amount of drug on them.

Participants/Inclusion and exclusion criteria

24 participants will be selected from non-smoking, not pregnant people with no history of heart, kidney and liver disease or dis functions with both sex (male&female). The ages and BMIs of participant should be in the range of 18-60 and 18-25 respectively.

Intervention groups

Both groups received in cross-over design medication and testing at two different cross-sections and Therefor,the test results are independent of individual differences and it will only show the difference in the formulation of the two drugs.

Main outcome variables

Cmax,Tmax, T1/2, Ke (Elemination)

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20200105046010N9**
Registration date: **2020-09-13, 1399/06/23**
Registration timing: **prospective**

Last update: **2020-09-13, 1399/06/23**
Update count: **0**

Registration date

2020-09-13, 1399/06/23

Registrant information

Name

Javad Shokri

Name of organization / entity

Country

Iran (Islamic Republic of)

Phone

+98 41 3661 4125

Email address

shokri.j@gmail.com

Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2020-09-24, 1399/07/03

Expected recruitment end date

2021-04-23, 1400/02/03

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

In- Vivo Bioequivalence study of Levodopa/Carbidopa/Entecapone tablet 200/50/200mg Fanda Pharma (Staparkin 200/50/200mg) with brand drugs (Stalevo 200/50/200mg Novartis, Germany) in Iranian healthy volunteers.

Public title

Study of bioequivalence of Levodopa/Carbidopa/Entecapone tablet 200/50/200mg Fanda Pharma (Staparkin 200/50/200mg) and foreign samples on 24 healthy Iranian volunteers.

Purpose

Treatment

Inclusion/Exclusion criteria

Inclusion criteria:

General health (liver , heart , kidney) Body mass index (18-28) Informed consent Age (18-60)

Exclusion criteria:

Smoking A history of cardiovascular disease A history of liver & kidney disease Pregnancy Alcohol & Drug addiction Hypersensitivity to the drug

Age

From **18 years** old to **60 years** old

Gender

Both

Phase

Bioequivalence

Groups that have been masked

- Participant

Sample size

Target sample size: **24**

Randomization (investigator's opinion)

Randomized

Randomization description

Individuals are randomly selected with advertising 24 volunteers categorized in two sequences randomly.the type of drug (Sample and Brand drug) will prescribe with lottery.The number of individuals will be randomly selected and the first twelve will be selected as the first sequence and the second twelve will be selected as the second sequence.

Blinding (investigator's opinion)

Single blinded

Blinding description

This study is a blind side clinical trial (volunteers). Staparkin and Stalevo® are removed from their packaging by the executor and placed in similar and coded cans. Volunteers will not be informed about receiving the brand or test dosage form

Placebo

Not used

Assignment

Crossover

Other design features

Tow period / Tow sequence with a washout time

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee

Tabriz University of Medical Sciences Ethics Committee

Street address

Tabriz. No.48,Ferdows street, Ferdowsi Sq.

City

Tabriz

Province

East Azarbaijan

Postal code

51678744

Approval date

2020-06-22, 1399/04/02

Ethics committee reference number

IR.TBZMED.REC.1399.314

Health conditions studied

1

Description of health condition studied

In this study the bioequivalence of test and brand of Staperkin will be evaluated.

ICD-10 code

ICD-10 code description

Primary outcomes

1

Description

Plasma drug concentration

Timepoint

Hour

Method of measurement

Blood sampling

Secondary outcomes

empty

Intervention groups

1

Description

Intervention group: Single dose of levodopa / carbidopa / entocapone citalopram 200/200/200 mg tablets (TALEVO® 200/50 / 200mg. NOVARTIS, Germany) Pharmaceutical Company as a reference product.

Category

Treatment - Drugs

2

Description
Intervention group: Single dose of Levodopa / Kirby Dopa / Entapapon Citalopram 200/50/200 mg Fanda Pharmaceutical Company (STAPARKIN® 200/50/200) as a test product.
Category
Treatment - Drugs

Recruitment centers

1

Recruitment center
Name of recruitment center
Simin Baspar Teyf Gostar Company
Full name of responsible person
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Sponsors / Funding sources

1

Sponsor
Name of organization / entity
Tabriz University of Medical Sciences
Full name of responsible person
Aliakbar Sari Sarraf
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No. 323, Second Floor, between Vazra St. and Valiasr St., Shahid Beheshti St., Tehran
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3188115981
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Grant name
Grant code / Reference number
Is the source of funding the same sponsor organization/entity?
No
Title of funding source
Tabriz University of Medical Sciences
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
Other

Person responsible for general inquiries

Contact
Name of organization / entity
Tabriz University of Medical Sciences
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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

These date are as secure between researcher and related industries.

Study Protocol

No - There is not 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

Yes - There is a plan to make this available

Title and more details about the data/document

Only protocol and methods of study are sharable.

When the data will become available and for how long

After finishing of the protocol (Probably 6 months receiving IRCT code)

To whom data/document is available

Pharmaceutical and medical sciences researchers.

Under which criteria data/document could be used

Projects information's for any publications is not allowed.

From where data/document is obtainable

Contact with E-mail of the main researcher.

What processes are involved for a request to access data/document

Personal and academic details and the aim of the request.

Comments