# Clinical Trial Protocol
# Iranian Registry of Clinical Trials

16 Sep 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**
Javad Shokri
**Street address**
No.48, Ferdows Street
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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
**Street address**
No. 323, Second Floor, between Vazra St. and Valiasr St., Shahid Beheshti St., Tehran
**City**
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**Province**
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3188115981
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+98 21 8604 6304
**Email**
info@Fandapharma.ir
**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
**Full name of responsible person**
Javad Shokri
**Position**
Professor
**Latest degree**
Ph.D.
**Other areas of specialty/work**
Medical Pharmacy
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## Person responsible for scientific inquiries

**Contact**
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Professor
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## Person responsible for updating data

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**Phone**

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**Email**

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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**