# Clinical Trial Protocol
# Iranian Registry of Clinical Trials

02 Jul 2026

## Randomized, single-dose, crossover comparative bioequivalence study of Linagliptin 5 mg tablets of Alhavi pharmaceutical co. and Boehringer in 24 healthy male under fasting conditions

### Protocol summary

**Study aim**
Bioequivalence study of Linagliptin 5 mg tablets of Alhavi pharmaceutical co. and Trajenta 5 mg tablet of Boehringer.

**Design**
Randomized, single-dose, crossover comparative bioequivalence study of Linagliptin 5 mg tablets of Alhavi Pharmaceutical Co. and Boehringer in 24 healthy male under fasting conditions

**Settings and conduct**
Study place: Hakim Farabi Clinic. Place for Blood and plasma sample analysis: Radin laboratory, Tabriz. Twenty four healthy male volunteers received each of two test or reference Linagliptin tablets in random sequence according to the randomization schedule. Receiving drug periods were 5 weeks apart from each other and after the washout period, subjects received the other product. Blood samples were taken from all participants before receiving the drug and 72 hours after that at determined time points for pharmacokinetic evaluations.

**Participants/Inclusion and exclusion criteria**
• Healthy subjects (male) between 18 – 45 years of age and Body Mass Index (BMI) between 18.5 and 30 (inclusive), calculated as kg/m2. • Subjects with no significant diseases or clinically significant abnormal findings during screening, medical history, clinical examination and laboratory evaluations. • Known hypersensitivity to linagliptin or inactive ingredients. • Subjects with a known history of allergic reaction.

**Intervention groups**
Intervention group 1 (test): Linagliptin 5 mg tablet, produced by Alhavi pharmaceutical co. is the test product. In each period, 12 of 24 subjects will be given single oral dose of this product. Intervention group 2 (Reference): Linagliptin 5 mg tablet, produced by Boehringer is the reference product. In each period, 12 of 24 subjects will be given single oral dose of this product.

**Main outcome variables**
Cmax, AUC

### General information

**Reason for update**

**Acronym**

**IRCT registration information**
IRCT registration number: **IRCT20180620040164N4**
Registration date: **2020-08-04, 1399/05/14**
Registration timing: **retrospective**

Last update: **2020-08-04, 1399/05/14**
Update count: **0**

**Registration date**
2020-08-04, 1399/05/14

**Registrant information**

**Name**
Behzad Montaha Sangari

**Name of organization / entity**
Noor research and educational institute (Tavan)

**Country**
Iran (Islamic Republic of)

**Phone**
+98 21 6600 7026

**Email address**
info@tavaninstitute.ir

**Recruitment status**
**Recruitment complete**

**Funding source**

**Expected recruitment start date**
2020-05-04, 1399/02/15

**Expected recruitment end date**
2020-05-20, 1399/02/31

**Actual recruitment start date**
empty

**Actual recruitment end date**
empty
**Trial completion date**
empty

**Scientific title**
Randomized, single-dose, crossover comparative bioequivalence study of Linagliptin 5 mg tablets of Alhavi pharmaceutical co. and Boehringer in 24 healthy male under fasting conditions

**Public title**
Bioequivalence study of Linagliptin 5 mg tablets in 24 healthy male under fasting conditions
**Purpose**
Treatment
**Inclusion/Exclusion criteria**
**Inclusion criteria:**
Healthy subjects (male) between 18 – 45 years of age and Body Mass Index (BMI) between 18.5 and 30 (inclusive), calculated as kg/m2. Subjects with no significant diseases or clinically significant abnormal findings during screening, medical history, clinical examination and laboratory evaluations. Subjects with normal ECG and vital signs. Subjects who agree with patient consent form.
**Exclusion criteria:**
Known hypersensitivity to linagliptin or inactive ingredients Acute and chronic cardiovascular, respiratory, gastrointestinal diseases, neuroendocrine disorders, blood system disorders and renal or hepatic impairment Acute infectious diseases less than 1 weeks prior to the start of the study 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 Subjects who have a history of alcohol or substance abuse within the last 5 years Heavy drinker of alcohol, 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 **18 years** old to **45 years** old
**Gender**
Male

**Phase**
Bioequivalence
**Groups that have been masked**
*No information*
**Sample size**
Target sample size: **24**
More than 1 sample in each individual
Number of samples in each individual: **26**
In each period, 13 blood samples are collected from each subject and this study includes 2 periods.
**Randomization (investigator's opinion)**
Randomized
**Randomization description**
The order of receiving the test product or reference for each subject in each time period was determined based on the randomization program. The randomization program was developed using randomization software based on the number assigned to each subject. The number assigned to each subject was based on the priority of being on the list of subjects for screening.
**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 Shahid Beheshti University of Medical Sciences
**Street address**
7th Floor, Builing No.2, Shahid Beheshti University of Medical Sciences, Arabi Ave, Daneshjoo Blvd, Velenjak
**City**
Tehran
**Province**
Tehran
**Postal code**
19839-63113
**Approval date**
2020-05-31, 1399/03/11
**Ethics committee reference number**
IR.SBMU.PHARMACY.REC.1399.046

## Health conditions studied

### 1

**Description of health condition studied**
Bioequivalence investigation of the generic (Alhavi pharmaceutical co.) Linagliptin 5 mg tablet with brand (Boehringer) Trajenta 5 mg tablet.
**ICD-10 code**
**ICD-10 code description**

## Primary outcomes

### 1

**Description**
Peak Plasma Concentration (Cmax)
**Timepoint**
During 2 months 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**
During 2 months 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: Intervention group (test): Linagliptin 5 mg tablet, produced by Alhavi pharmaceutical co. is the test product. In each period, 12 of 24 subjects will be given single oral dose of this product.
**Category**
Treatment - Drugs

**2**

**Description**
Intervention group (Reference): Linagliptin 5 mg tablet, produced by Boehringer is the reference product. In each period, 12 of 24 subjects will be given single oral dose of this product.
**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, Sallor city
**City**
Eslamshahr
**Province**
Tehran
**Postal code**
4635314588
**Phone**
+98 21 5647 9253
**Email**
mina.hasanabadi@yahoo.com

## Sponsors / Funding sources

**1**

**Sponsor**
**Name of organization / entity**
Alhavi pharmaceutical co.
**Full name of responsible person**
Mohamad masoud Alimorad
**Street address**
12 km of Karaj road
**City**
Tehran
**Province**
Tehran
**Postal code**
141551538
**Phone**
+98 21 4490 5056
**Email**
info@alhavipharma.com
**Grant name**
**Grant code / Reference number**
**Is the source of funding the same sponsor organization/entity?**
No
**Title of funding source**
Alhavi 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**
pharmacy
**Street address**
Unit 34, No. 69, Habibzadegan Ave., Teymuri St.,Tehran, Iran
**City**
Tehran
**Province**
Tehran
**Postal code**
1459926609

**Phone**
+98 21 6600 4027
**Email**
info@tavaninstitute.ir

## Person responsible for scientific inquiries

**Contact**
**Name of organization / entity**
Tavan Institute
**Full name of responsible person**
Seyed Mohsen Foroutan
**Position**
Principal investigator
**Latest degree**
Ph.D.
**Other areas of specialty/work**
Medical Pharmacy
**Street address**
Unit 34, No. 69, Habibzadegan Ave., Teymuri St.
**City**
Tehran
**Province**
Tehran
**Postal code**
1459926609
**Phone**
+98 21 6600 4027
**Email**
info@tavaninstitute.ir

## Person responsible for updating data

**Contact**
**Name of organization / entity**
Tavan Institute
**Full name of responsible person**
Ali Aghaei
**Position**
master
**Latest degree**
Master
**Other areas of specialty/work**
pharmacy
**Street address**
Unit 34, No. 69, Habibzadegan Ave., Teymuri St.
**City**
Tehran
**Province**
Tehran
**Postal code**
1459926609
**Phone**
+98 21 6600 4027
**Email**
info@tavaninstitute.ir

## Sharing plan

**Deidentified Individual Participant Data Set (IPD)**
Undecided - It is not yet known if there will be a plan to make this available
**Study Protocol**
Undecided - It is not yet known if there will be a plan to make this available
**Statistical Analysis Plan**
Undecided - It is not yet known if there will be 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