Clinical Trial Protocol
Iranian Registry of Clinical Trials

26 Jun 2026

Comparative bioequivalence study of Hydrochlorothiazide 50 mg Tablet of Karen. and APO-HYDRO® of Apotex INC 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 Hydrochlorothiazide 50 mg Tablet formulation.

Design
Non-blinded, randomized, crossover in vivo bioequivalence study in 24 healthy males under fasting conditions. Block randomization is used.

Settings and conduct
In each period, volunteers will receive a single dose of the treatment in the Noor Research and Development Institute (Tarasht, Tehran). 2 dosing periods will be separated by a 7-day washout period.

Participants/Inclusion and 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. Exclusion Criteria: Subjects with a history of known hypersensitivity to hydrochlorothiazide or other sulfonamide drugs, associated acute or chronic infections; Volunteers who have water and electrolyte disorders, including low blood potassium and sodium, history of diarrhea or vomiting, headache, muscle cramps or weakness in the past two weeks;

Intervention groups
Intervention group 1: Hydrochlorothiazide 50 mg Tablet, produced by Karen. is the test product. In each period, 12 of 24 subjects will be given a single oral dose of this product. Intervention group 2: APO-HYDRO 50 mg Tablet, produced by Apotex INC 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: **IRCT20180620040164N51**
Registration date: **2023-10-21, 1402/07/29**
Registration timing: **prospective**

Last update: **2023-10-21, 1402/07/29**
Update count: **0**

Registration date
2023-10-21, 1402/07/29

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
2023-11-16, 1402/08/25

Expected recruitment end date
2023-12-01, 1402/09/10

Actual recruitment start date
empty

Actual recruitment end date
empty

Trial completion date

empty

Scientific title
Comparative bioequivalence study of Hydrochlorothiazide 50 mg Tablet of Karen. and APO-HYDRO® of Apotex INC as reference in 24 healthy male under fasting.

Public title
Comparative in vivo evaluation of 2 Hydrochlorothiazide 50 mg Tablet formulations.

Purpose
Treatment

Inclusion/Exclusion criteria

Inclusion criteria:
Healthy volunteers Between 18 – 45 years of age and Body Mass Index (BMI) within 15% of normal range according to the accepted normal values between 18 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 vital signs.

Exclusion criteria:
Subjects with a history of known hypersensitivity to hydrochlorothiazide or other sulfonamide drugs, associated acute or chronic infections; Volunteers who have water and electrolyte disorders, including low blood potassium and sodium, history of diarrhea or vomiting, headache, muscle cramps or weakness in the past two weeks; blood pressure in standing position and after at least 5 minutes of rest, systole less than 100 or more than 140 mmHg and diastole less than 60 or more than 90 mmHg); Smoking more than 10 cigarettes per day and could not tolerate cigarette cessation during each clinical period; volunteers with a history of difficulty with donating blood; 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**

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 numbers (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,School of Pharmacy,Nursing&Midwifery-Shahid Beheshti University of medical sciences

Street address
Niayesh Highway, Valiasr Ave, Tehran, Iran

City
Tehran

Province
Tehran

Postal code
1996835113

Approval date
2023-10-09, 1402/07/17

Ethics committee reference number
IR.SBMU.PHARMACY.REC.1402.130

Health conditions studied

1

Description of health condition studied
Essential (primary) hypertension

ICD-10 code
I10

ICD-10 code description
Essential (primary) hypertension

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, 4.5, 5, 6, 8, 12, 24, 36 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, 4.5, 5, 6, 8, 12, 24, 36 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: Hydrochlorothiazide 50 mg Tablet , produced by Karen. is the test product. In each period, 12 of 24 subjects will be given single oral dose of this product. After 07-day wash-out period the intervention 2 will be given to these subjects.
Category
Treatment - Drugs

2

Description
Intervention group 2: APO-HYDRO 50 mg tablet, produced by Apotex INC is the reference product. In each period, 12 of 24 subjects will be given single oral dose of this product. After 07-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
Noor Research & Development Institute (Tavan)
Full name of responsible person
Ali Aghaei
Street address
Sharif Innovation Station, North Habibollah Street, Hosseini Square, Teymoury Street, Tarasht.
City
Tehran
Province
Tehran
Postal code
1459926609
Phone
+98 21 6600 4027
Email
info@tavaninstitute.ir

Sponsors / Funding sources

1

Sponsor
Name of organization / entity
Karen Pharma and Food Supplement Co.
Full name of responsible person
Zahra Mortazavi
Street address
No: 3, Western Nahid st. Africa Blvd.
City
Tehran
Province
Tehran
Postal code
۱۴۵۹۹۶۵۲۰۴
Phone
+98 21 2620 4283
Email
info@karenpharma.com
Grant name
Grant code / Reference number
Is the source of funding the same sponsor organization/entity?
Yes
Title of funding source
Karen Pharma and Food Supplement 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
Sharif innovation station, North Habibollah Street, Hosseini Square, Teymoury Street, Tarasht.
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
Sharif innovation station, North Habibollah Street, Hosseini Square, Teymoury Street, Tarasht.
City
Tehran
Province
Tehran
Postal code
1459926609
Phone
+98 21 6600 4027
Email
mforoutan@gmail.com

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
Sharif innovation station, North Habibollah Street, Hosseini Square, Teymoury Street, Tarasht.
City
Tehran
Province
Tehran
Postal code
1459926609
Phone
+98 21 6600 4027
Email
partochem@gmail.com

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
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
No - There is not a plan to make this available