Clinical Trial Protocol
Iranian Registry of Clinical Trials

01 Nov 2026

A randomized, open label, two treatments, two periods, two sequence, single dose, crossover, bioequivalence study of Hydrochlorothiazide 50mg tablet of Toliddaru Pharm Co., IRAN in comparison of HCT Dexcel 50mg tablet of Dexcel in 24 healthy adult subjects under fasting condition

Protocol summary

Study aim

Bioequivalence study of single dose of test formulation (one tablet of Hydrochlorothiazide 50mg produced by Toliddaru Pharm Co., IRAN in comparison of reference product (one tablet of HCT Dexcel 50mg) by means of AUC0-t and Cmax in healthy adult human subjects under fasting conditions.

Design

A randomized, open label, single dose, crossover, bioequivalence study in 24 healthy subjects under fasting condition

Settings and conduct

This study is carried out in Core Research Center of Zahedan University of Medical Sciences located in Imam Ali Hospital in Zahedan. There is a separate space for sampling and forecasting emergency situations in order to accommodate and rest the volunteers. This crossover and open label study was performed on 24 healthy volunteers. The volunteers' health is verified by the project physician prior to entry into the study, and the volunteers' status is regularly monitored by the project physician on the day of drug administration. This study will be covered by insurance in order to compensate for any adverse effects.

Participants/Inclusion and exclusion criteria

Main Inclusion criteria: Healthy subjects aged between 18 -50 years old and weighted between 50 – 100 kg\\
Main exclusion criteria: History of GI surgery; Donation a unit of blood or participated in another clinical trial within the last two months; History of drug or alcohol abuse; Used any medication within 7- 14 days before the first treatment;

Intervention groups

Intervention: Single dose of one Hydrochlorothiazide 50mg tablet of Toliddaru Pharm Co., IRAN Control: Single dose of one HCT Dexcel 50mg tablet of Dexcel

Main outcome variables

Plasma concentration of Hydrochlorothiazide at 0 (before dosing), 30, 60, 80, 100, 120, 140, 160, 180, 200, 220 min. and 4.0, 6.0, 8.0, 10.0 & 24.0 hr. after dosing

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20190706044111N21**
Registration date: **2021-05-24, 1400/03/03**
Registration timing: **prospective**

Last update: **2021-05-24, 1400/03/03**
Update count: **0**

Registration date

2021-05-24, 1400/03/03

Registrant information

Name

Ladan Tayebi

Name of organization / entity

Pars Biopharmacy Research Co.

Country

Iran (Islamic Republic of)

Phone

+98 21 8895 6061

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Recruitment status

Recruitment complete

Funding source

Expected recruitment start date
2021-10-23, 1400/08/01
Expected recruitment end date
2022-06-20, 1401/03/30
Actual recruitment start date
empty
Actual recruitment end date
empty
Trial completion date
empty

Scientific title
A randomized, open label, two treatments, two periods, two sequence, single dose, crossover, bioequivalence study of Hydrochlorothiazide 50mg tablet of Toliddaru Pharm Co., IRAN in comparison of HCT Dexcel 50mg tablet of Dexcel in 24 healthy adult subjects under fasting condition

Public title
Bioequivalence study of Hydrochlorothiazide 50mg tablet of Toliddaru Pharm Co., IRAN
Purpose
Other
Inclusion/Exclusion criteria
Inclusion criteria:
- Aged between 18 - 50 years - Body weight between 50 – 100 kg - Having good health on the basis of medical history and physical & clinical examination - Understand the procedures and give written informed consent
Exclusion criteria:
Subject had undergone surgery of the gastro-intestinal tract Subject had donated a unit of blood or participated in another clinical trial, within the last two months before the first treatment. Subject had a history of drug or alcohol abuse. Subject who smokes more than 10 cigarettes per day. Subject had used any prescription medication within 14 days, or any non-prescription medication within 7 days, before the first treatment.
Age
From **18 years** old to **50 years** old
Gender
Both

Phase
Bioequivalence
Groups that have been masked
No information
Sample size
Target sample size: **48**
More than 1 sample in each individual
Number of samples in each individual: **2**
Each volunteer, 2 times take medicine in the study. One-time test product and the other time reference product with at least one week wash-out period.
Randomization (investigator's opinion)
Randomized
Randomization description
Due to the cross-over study, Using Excel software, each subject will be randomly assigned to one of the two sequence AB or BA in a balanced manner.command rand command.
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 Zahedan University of medical Sciences
Street address
Dr. Hessabi square Zahedan University of Medical Sciences
City
Zahedan
Province
Sistan-va-Balouchestan
Postal code
9816743463
Approval date
2021-04-04, 1400/01/15
Ethics committee reference number
IR.ZAUMS.REC.1400.016

Health conditions studied

1

Description of health condition studied
High blood pressure and edema
ICD-10 code
Y54.5
ICD-10 code description
Diuretics

Primary outcomes

1

Description
Plasma concentration of Hydrochlorothiazide
Timepoint
at 0 (before dosing), 30, 60, 80, 100, 120, 140, 160, 180, 200, 220 min. and 4.0, 6.0, 8.0, 10.0 & 24.0 hr. after dosing
Method of measurement
High Performance liquid Chromatography (HPLC)

Secondary outcomes

empty

Intervention groups

1

Description
Intervention group:Single dose of one Hydrochlorothiazide 50mg tablet of Toliddaru Pharm Co., IRAN
Category
Other

2

Description
Control group: Single dose of one HCT Dexcel 50mg tablet of Dexcel
Category
Other

Recruitment centers

1

Recruitment center
Name of recruitment center
Core Research Lab. of ZAUMS
Full name of responsible person
Marzyeh Ghasemi
Street address
Emam Ali Hospital, Salamat Blv., Khalij-e-Fars Highway
City
Zahedan
Province
Sistan-va-Balouchestan
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9816743111
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+98 54 3329 5664
Fax
+98 54 3329 5665
Email
crl@zaums.ac.ir
Web page address
http://crl.zaums.ac.ir/

Sponsors / Funding sources

1

Sponsor
Name of organization / entity
Toliddaru Pharm. co.
Full name of responsible person
Alireza Dabirsyaghi
Street address
Shahid Yadegar St. ; Saveh Road
City
Tehran
Province
Tehran
Postal code
1371616314
Phone
+98 21 6117 1554
Fax
+98 21 6662 0175
Email
info@toliddaru.ir
Web page address
http://www.toliddaru.ir
Grant name
Grant code / Reference number
Is the source of funding the same sponsor organization/entity?
Yes
Title of funding source
Toliddaru Pharm. 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
Pars Biopharmacy Research Co.
Full name of responsible person
Ladan Tayebi
Position
Managing Director
Latest degree
Medical doctor
Other areas of specialty/work
Medical Pharmacy
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Person responsible for updating data

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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
Undecided - It is not yet known if there will be a plan to make this available
Clinical Study Report
Undecided - It is not yet known if there will be a plan to make this available
Analytic Code
Undecided - It is not yet known if there will be a plan to make this available
Data Dictionary
Undecided - It is not yet known if there will be a plan to make this available