Clinical Trial Protocol
Iranian Registry of Clinical Trials

10 Jun 2026

A randomized, open label, two treatments, two periods, two sequence, single dose, crossover, bioequivalence study of Hydrochlorothiazide (2*25mg) tablet of Amin Pharm Co., IRAN in comparison of Esidrex (2*25mg) tablet of Juvice in 24 healthy adult subjects under fasting condition

Protocol summary

Study aim
A randomized, crossover bioequivalence study of single dose of test formulation (two tablets of Hydrochlorothiazide 25mg produced by ،Amin Pharm Co., IRAN) in comparison of reference product (two tablets of Esidrex 25mg of Juvice) by means of AUC0-t and Cmax in healthy adult human subjects under fasting conditions.

Design
A randomized, crossover bioequivalence study of single dose of test formulation (two tablets of Hydrochlorothiazide 25mg) produced by ،Amin Pharm Co., IRAN in comparison of reference product (two tablets of Esidrex 25mg) in 24 healthy adult human subjects under fasting conditions.

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

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: Clinically relevant deviations from normal; 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 two Hydrochlorothiazide 25mg tablet of Amin Pharm Co., IRAN Control: Single dose of two Esidrex 25mg tablets of Juvice

Main outcome variables
Plasma concentration of Hydrochlorothiazide at 0 (before dosing), 0.5, 1.0, 1.5, 2.0, 2.5, 3.0, 3.5, 4.0, 5.0, 6.0, 8.0, 10.0, 24.0 & 48.0 hr. after dosing

General information

Reason for update

Acronym

IRCT registration information
IRCT registration number: **IRCT20190706044111N39**
Registration date: **2025-01-28, 1403/11/09**
Registration timing: **prospective**

Last update: **2025-01-28, 1403/11/09**
Update count: **0**

Registration date
2025-01-28, 1403/11/09

Registrant information

Name
Ladan Tayebi

Name of organization / entity
Pars Biopharmacy Research Co.

Country
Iran (Islamic Republic of)

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+98 21 8895 6061

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Recruitment status
Recruitment complete

Funding source

Expected recruitment start date
2025-03-21, 1404/01/01
Expected recruitment end date
2026-03-20, 1404/12/29
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 (2*25mg) tablet of Amin Pharm Co., IRAN in comparison of Esidrex (2*25mg) tablet of Juvice in 24 healthy adult subjects under fasting condition

Public title
Bioequivalence study of Hydrochlorothiazide 25mg tablet of Amin 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: **24**
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
Using Excel software, each subject will be randomly assigned to one of the two sequence AB or BA in a balanced manner.
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
2025-01-26, 1403/11/07
Ethics committee reference number
IR.ZAUMS.REC.1403.421

Health conditions studied

1

Description of health condition studied
High blood pressure
ICD-10 code
ICD-10 code description

Primary outcomes

1

Description
Plasma concentration of Hydrochlorothiazide
Timepoint
at 0 (before dosing), 0.5, 1.0, 1.5, 2.0, 2.5, 3.0, 3.5, 4.0, 5.0, 6.0, 8.0, 10.0, 24.0 & 48.0 hr. after dosing
Method of measurement
High Performance Liquid Chromatography (HPLC)

Secondary outcomes

empty

Intervention groups

1

Description
Intervention group: Hydrochlorothiazide, two 25mg tablets, produced by Amin Pharm Co (IRAN), single dose.
Category
Other

2

Description
Control group: Esidrex, two 25mg tablets, produced by Juvice company, single dose
Category
Other

Recruitment centers

1

Recruitment center
Name of recruitment center
Core Research Lab. of ZAUMS
Full name of responsible person
Majid Sartipi
Street address
Emam Ali Hospital, Salamat Blv., Khalij-e-Fars Highway
City
Zahedan
Province
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9816743111
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+98 54 3329 5664
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+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
Amin Pharm. Co.
Full name of responsible person
Shahab Pasha Zanous
Street address
Nejatbakhsh Boulevard
City
Falavarjan
Province
Isfehan
Postal code
8459143344
Phone
+98 31 3725 2900
Fax
+98 31 3725 2898
Email
info@aminpharma.com
Web page address
https://aminpharma.com
Grant name
Grant code / Reference number
Is the source of funding the same sponsor organization/entity?
Yes
Title of funding source
Amin 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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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