Clinical Trial Protocol
Iranian Registry of Clinical Trials

10 Jun 2026

A randomized, open label, single dose, crossover, bioequivalence study of Prazosin 5mg tablet produced by Amin Pharm Co., IRAN in comparison owith MiniPress 5mg tablet produced by Laphal Co. in 24 healthy adult subjects under fasting condition

Protocol summary

Study aim

A randomized, crossover bioequivalence study of single dose of test formulation (Prazosin 5mg tablet of Amin Pharm Co., IRAN) in comparison of reference product (MiniPress 5mg tablet of Laphal) 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; weighted between 50 – 100 kg. Main exclusion criteria: History of the gastro-intestinal tract 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 Prazosin 5mg tablet of Amin Pharm Co, IRAN Control: Single dose of one MiniPress 5mg tablet of Laphal

Main outcome variables

Plasma concentration of Prazosin

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20190706044111N27**
Registration date: **2022-01-12, 1400/10/22**
Registration timing: **prospective**

Last update: **2022-01-12, 1400/10/22**
Update count: **0**

Registration date

2022-01-12, 1400/10/22

Registrant information

Name
Ladan Tayebi
Name of organization / entity
Pars Biopharmacy Research Co.
Country
Iran (Islamic Republic of)
Phone
+98 21 8895 6061
Email address
l.tayebi@parsbiopharmacy.com

Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2022-04-20, 1401/01/31

Expected recruitment end date

2023-04-20, 1402/01/31

Actual recruitment start date
empty
Actual recruitment end date
empty
Trial completion date
empty

Scientific title
A randomized, open label, single dose, crossover, bioequivalence study of Prazosin 5mg tablet produced by Amin Pharm Co., IRAN in comparison owith MiniPress 5mg tablet produced by Laphal Co. in 24 healthy adult subjects under fasting condition

Public title
Bioequivalence study of Prazosin 5mg 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:
History of the gastro-intestinal tract surgery Subject with a history of blood donation or participation in another clinical trial, within the last two months before the first treatment Subject with a history of drug or alcohol abuse. Subject who smokes more than 10 cigarettes per day. Subject with a history of disease leading to using drug 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 the rand command in Excel software, one of the sequences AB (test-reference product) or BA (reference-test product) is randomly assigned to each volunteer at random.
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
Zahedan University of Medical Sciences; Dr. Hessabi square
City
Zahedan
Province
Sistan-va-Balouchestan
Postal code
9816743463
Approval date
2021-12-12, 1400/09/21
Ethics committee reference number
IR.ZAUMS.REC.1400.309

Health conditions studied

1

Description of health condition studied
Hypertension
ICD-10 code
I10
ICD-10 code description
Essential (primary) hypertension

Primary outcomes

1

Description
Plasma concentration of prazosin after single dose of 5mg prazosin tablet
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 hr. after dosing
Method of measurement
High Performance Liquid Chromatography (HPLC)

Secondary outcomes

empty

Intervention groups

1

Description

Intervention group: Prazosin, one 5mg tablet, produced by Amin Pharm Co. (IRAN), single dose

Category

Other

2

Description

Control group: MiniPress, one 5mg tablet, produced by Laphal company, single dose.

Category

Other

Recruitment centers

1

Recruitment center

Name of recruitment center

Core Research Lab. of Zahedan University of Medical Sciences

Full name of responsible person

Marzyeh Ghasemi

Street address

Emam Ali Hospital, Salamat Blv., Khalij-e-Fars Highway

City

Zahedan

Province

Sistan-va-Balouchestan

Postal code

9816743111

Phone

+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

Amin Pharm. Co.

Full name of responsible person

Mohammad Mahdy Hoghoughi

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

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

Street address

First floor, No 5, Saeidi Dead-end alley, Palestin Ave.

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Person responsible for scientific inquiries

Contact

Name of organization / entity

Pars Biopharmacy Research Co.

Full name of responsible person

Ladan Tayebi

Position

Managing Director

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Person responsible for updating data

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Web page address

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