Clinical Trial Protocol
Iranian Registry of Clinical Trials

18 Sep 2026

Bioequivalence study of Indapamide 5.1 mg tablet manufactured by Darou darman Arang versus originator brand in healthy volunteers in the fasted condition

Protocol summary

Study aim

Bioequivalence Study of Indapamide 5.1 mg tablet manufactured by Darou darman Arang company versus originator brand (Natrilix) manufactured by Servier company

Design

Bioequivalence study, crossover, single-blinded, 24 healthy volunteers. Simple randomization was used for randomization

Settings and conduct

The study is a single-blinded (Volunteer), cross-over and fasting, and on two series of healthy volunteers. The study will be done in two periods (72h). The interval between these two periods is two weeks. The candidates were divided into two groups in the first round of the study. the first group receives a test tablet and the second group receives a brand tablet. the volunteers don't know about receiving brand or test products. Blood samples are collected immediately before and after drug administration by volunteers. Then, drug extraction is done and samples are ready for analysis. These steps are performed in Radin Laboratory in Tabriz.

Participants/Inclusion and exclusion criteria

Inclusion criteria: General Health (Liver, Heart, and Kidney); Body Mass Index (18-28); Informed consent; age (18-55 years old). Exclusion criteria: smoking; history of cardiovascular disease; history of liver and kidney disease; alcohol and drug addiction; history of allergy to Indapamide

Intervention groups

Intervention group 1: Natrilix 5.1mg tablet as a reference
Intervention group 2: Indapamide 5.1 mg as a test

Main outcome variables

Maximum drug concentration, Time to reach maximum drug concentration

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20200105046010N84**
Registration date: **2023-10-03, 1402/07/11**
Registration timing: **prospective**

Last update: **2023-10-03, 1402/07/11**
Update count: **0**

Registration date

2023-10-03, 1402/07/11

Registrant information

Name

Javad Shokri

Name of organization / entity

Country

Iran (Islamic Republic of)

Phone

+98 41 3661 4125

Email address

shokri.j@gmail.com

Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2023-10-07, 1402/07/15

Expected recruitment end date

2024-03-19, 1402/12/29

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title
Bioequivalence study of Indapamide 5.1 mg tablet manufactured by Darou darman Arang versus originator brand in healthy volunteers in the fasted condition

Public title
Bioequivalence study of Indapamide 5.1 mg tablet
Purpose
Treatment
Inclusion/Exclusion criteria
Inclusion criteria:
General Health (Liver, Heart, and Kidney) Body Mass Index (18-28) Informed consent Age (18-55 years old)
Exclusion criteria:
Smoking History of cardiovascular disease History of liver and kidney disease Alcohol and drug addiction History of allergy to Indapamide
Age
From **18 years** old to **55 years** old
Gender
Both

Phase
Bioequivalence
Groups that have been masked

- Participant

Sample size
Target sample size: **24**
Randomization (investigator's opinion)
Randomized
Randomization description
Each candidate is assigned a number from 1 to 24. The numbers are written on a plastic ball, poured into a container, and mixed. The balls are then removed randomly from the container and divided in 2 groups of 12 test (A) and reference (B) drug recipients, then in the second phase, groups A and B will be cross-referenced to the test and drug recipients.
Blinding (investigator's opinion)
Single blinded
Blinding description
This study is a single-blinded clinical trial (volunteers). Darou darman Arang's Indapamide and Originator brand tablets are removed from their packaging by the executor and placed in similar and coded cans. Volunteers will not be informed about receiving the brand or test dosage form
Placebo
Not used
Assignment
Crossover
Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee
Name of ethics committee
Tabriz University of Medical Sciences ethics committe
Street address
Deputy of research and technology, 3rd floor, No 2 Central Building, Tabriz University of Medical Sciences, Golgasht Street
City
Tabriz
Province
East Azarbaijan
Postal code
5165665931
Approval date
2023-09-04, 1402/06/13
Ethics committee reference number
IR.TBZMED.REC.1402.453

Health conditions studied

1

Description of health condition studied
This study is performed on healthy volunteers.
ICD-10 code
ICD-10 code description

Primary outcomes

1

Description
The concentration of the drug in blood
Timepoint
Pre-dose, 1, 2, 3, 4, 6, 8, 9, 10, 12, 16, 24, 36, 48 and 72 h after drug administration
Method of measurement
Liquid Chromatography Mass-Mass

Secondary outcomes

1

Description
Time to reach maximum blood concentration
Timepoint
After intervention
Method of measurement
The time to reach the maximum drug concentration in blood is recorded

2

Description
Extent of absorption
Timepoint
After intervention
Method of measurement
Calculation of area under curve of concentration -time

Intervention groups

1

Description
Intervention group: single dose, one oral tablet 5.1mg(Natrilix) manufactured by Servier company, as a reference product
Category
Treatment - Drugs

2

Description
Intervention group: Single dose, one oral Indapamide 5.1 mg tablet manufactured by Darou darman Arang company as a test product
Category
Treatment - Drugs

Recruitment centers

1

Recruitment center
Name of recruitment center
Radin laboratory
Full name of responsible person
Javad Shokri
Street address
No.22, first floor, Azadi alley, Moalem st., Abureihan St
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5154995671
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shokri.j@gmail.com

Sponsors / Funding sources

1

Sponsor
Name of organization / entity
Darou darman Arang
Full name of responsible person
Alireza Mahbubian
Street address
Unit 1, No.1,West Saeb Tabrizi St., Sheikh Bahaei St., Molla Sadra St.
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Province
Tehran
Postal code
1993674855
Phone
+98 21 8805 4460
Email
info@arangpharm.com
Grant name
Grant code / Reference number
Is the source of funding the same sponsor organization/entity?
Yes
Title of funding source
Darou darman Arang
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
Tabriz University of Medical Sciences
Full name of responsible person
Javad Shokri
Position
Professor
Latest degree
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Other areas of specialty/work
Medical Pharmacy
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Sharing plan

Deidentified Individual Participant Data Set (IPD)
No - There is not a plan to make this available
Justification/reason for indecision/not sharing IPD
These data are as secure between researchers and related industries.
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