Clinical Trial Protocol
Iranian Registry of Clinical Trials

17 Sep 2026

In- Vivo Bioequivalence study of Trientine hard capsules 250 mg with brand drug (CYPRINE® 250 mg Merck & Co., Germany) in Iranian healthy volunteers.

Protocol summary

Study aim

In- Vivo Bioequivalence study of Trientine capsules 250 mg Nano Pajhoohan Pardis Pharmaceuticals with brand drug (CYPRINE® 250 mg Merck & Co., Germany) in Iranian healthy volunteers.

Design

Single dose, randomized, two sequences, two period crossover with a washout period.

Settings and conduct

This study will be conducted in single-dose, cross-over, and fasting, and on two sets of healthy volunteers. The study will be conducted in two periods of 72 hours. The interval between these two periods, which is called the wash-out time, is determined by the half-life of the drug plasma, which according to scientific sources should be at least 5 to 7 half-life of the drug in the case of the drug under study. The plan will take a week to clean up the drug, given the biological half-life of the drugs in the drug form. In the first round, candidates are divided into two groups, and the first group receives a test capsule and the second group receives similar capsules. Blood samples will be taken by the volunteer by the technician immediately after taking the drug, and the preparation steps of the samples, including plasma separation and drug extraction, are performed to analyze the amount of drug on them.

Participants/Inclusion and exclusion criteria

24 participants will be selected from non-smoking, not pregnant people with no history of heart, kidney, and liver disease or dysfunctions with both sexes (male&female). The ages and BMIs of the participants should be in the range of 18-60 and 18-28 respectively

Intervention groups

Single dose Trientine capsules 250 mg Nano Pajhoohan Pardis Pharmaceuticals Company with brand drugs (CYPRINE® 250 mg Merck & Co., Germany)

Main outcome variables

Determination of blood drug concentration

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20200105046010N34**
Registration date: **2021-07-27, 1400/05/05**
Registration timing: **registered_while_recruiting**

Last update: **2021-07-27, 1400/05/05**
Update count: **0**

Registration date

2021-07-27, 1400/05/05

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

2021-07-01, 1400/04/10

Expected recruitment end date

2022-01-30, 1400/11/10

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date
empty

Scientific title
In- Vivo Bioequivalence study of Trientine hard capsules 250 mg with brand drug (CYPRINE® 250 mg Merck & Co., Germany) in Iranian healthy volunteers.

Public title
En In-vivo Bioequivalence Capsule of Trientine tablet with brand drugs (CYPRINE® 250 mg Merck & Co., Germany).
Purpose
Treatment
Inclusion/Exclusion criteria
Inclusion criteria:
General health Body mass index(18-28) Informed consent Age(18-60)
Exclusion criteria:
Smoking A history of cardiovascular disease A history of liver & kidney disease Pregnancy Alcohol & Drug addiction Hypersensitivity to the drug
Age
From **18 years** old to **60 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
For this purpose, first, determine the total sample size (24 people), then write the names of the people on paper, and after folding in aluminum foil, pour it into a glass, and then randomly remove the papers and open the first 12 people in group A and the rest are selected as group B.
Blinding (investigator's opinion)
Single blinded
Blinding description
Candidates will be not aware of the test drug or brand name. In a one-blind study, information that could distort the test result is hidden from the candidates, but the person in charge of the test is aware of it. Trientine and Trientine 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 medications.
Placebo
Not used
Assignment
Crossover
Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee
Name of ethics committee
Ethics Committee, Tabriz University of Medical Sciences
Street address
Third floor of TUMS (Tabriz University of Medical Sciences) central building, Dneshgah St. Tabriz, Iran
City
Tabriz
Province
East Azarbaijan
Postal code
5166614766
Approval date
2021-05-17, 1400/02/27
Ethics committee reference number
IR.TBZMED.REC.1400.163

Health conditions studied

1

Description of health condition studied
Bio equivalence test
ICD-10 code
ICD-10 code description

Primary outcomes

1

Description
Determination of blood drug concentration.
Timepoint
Sampling times in this study will be 0, 1, 2, 2:30, 3, 3:20, 3:40, 4, 4:20, 4: 40, 5, 6, 8, 10, 12, 24, 48, 72 hours After prescribing the tablet.
Method of measurement
High Performance Liquid Chromatography with tandem mass spectroscopy detector

Secondary outcomes

empty

Intervention groups

1

Description
Intervention group: will receive one test drug capsule (Trientine capsule 250 mg Nanodaru Pharmaceuticals). Blood samples will be taken from the volunteers for 72 hours at the mentioned times after drug administration and the concentration of trientine in blood samples will be measured by liquid chromatography with mass spectroscopy detector.
Category

Treatment - Other

2

Description
Control group: will receive one test drug table (CYPRINE® 250 mg Merck & Co., Germany Pharmaceuticals). Blood samples will be taken from the volunteers for 72 hours at the mentioned times after drug administration and the concentration of cyprine in blood samples will be measured by liquid chromatography with mass spectroscopy detector.
Category
Treatment - Other

Recruitment centers

1

Recruitment center
Name of recruitment center
Simin Baspar Teyf Gostar Company
Full name of responsible person
Javad Shokri
Street address
No.48, Ferdos Street
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Tabriz
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5167874434
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+98 41 3384 2724
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Sponsors / Funding sources

1

Sponsor
Name of organization / entity
Nano Pajhoohan Pardis Co.
Full name of responsible person
Navid Gudarzi
Street address
No. 4 and 8, Tak Shomali St., Attar St., Vanak Square
City
Tehran
Province
Tehran
Postal code
1994754953
Phone
+98 21 8864 9082
Email
info@nanodaru.com
Grant name
Grant code / Reference number
Is the source of funding the same sponsor organization/entity?
Yes
Title of funding source
Nano Pajhoohan Pardis 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
Persons

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
Ph.D.
Other areas of specialty/work
Medical Pharmacy
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Person responsible for scientific inquiries

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Person responsible for updating data

Contact

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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 date are as secure between researcher 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

Yes - There is a plan to make this available

Title and more details about the data/document

Only protocol and methods of study are sharable

When the data will become available and for how long

Only protocol and methods of study are sharable.

To whom data/document is available

Pharmaceutical and medical sciences researchers

Under which criteria data/document could be used

Projects information's for any publications is not allowed.

From where data/document is obtainable

By email to the project manager (shokri.j@gmail.com)

What processes are involved for a request to access data/document

This information is confidential and is at the disposal of the project sponsor. Upon request, the information will be provided to the applicant by the contractor's email after the

Comments