Clinical Trial Protocol
Iranian Registry of Clinical Trials

07 Nov 2026

Bioequivalence study of the intravenous solution of Ferric carboxy maltose 50mg/ml (Ferririse)manufactured by Zistdaru Danesh versus originator brand (Ferinject) in healthy volunteers in the fasted condition

Protocol summary

Study aim

Bioequivalence study of the intravenous solution of Ferric carboxy maltose 50mg/ml (Ferririse)manufactured by Zistdaru Danesh versus originator brand (Ferinject) in healthy volunteers in the fasted condition

Design

Bioequivalence study with 2 intervention groups, Parallel, single-blinded, Two groups of 25 healthy volunteers. The rand function of Excel software was used for randomization.

Settings and conduct

The study is single-blinded, parallel, fasted, and on two series of healthy volunteers. The study will be done in one period (72h). The candidates are divided into two groups. the first group receives a test product and the second group receives a brand product. 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: Weight over 50 kg, Informed consent, Age (18-55 years old) Exclusion criteria: Pregnancy and breastfeeding, History of allergy to ferric carboxy maltose or similar drugs, Patients with high blood pressure, Blood loss in a way that leads to hemodynamic instability, receiving intravenous iron in the last 3-6 months.

Intervention groups

Intervention group 1: injection solution of ferric carboxy maltose 50 mg/ml manufactured by Vifor Pharma company as a reference Intervention group 2: injection solution of ferric carboxy maltose 50 mg/ml manufactured by Zistdaru Danesh company as a test.

Main outcome variables

Maximum drug concentration, Time to reach maximum concentration, Half-life of drug

General information

Reason for update

The FDA proposed protocol update at the end of 2024 for this study, which would allow for the study to be conducted in healthy volunteers at a low dose.

Acronym

IRCT registration information

IRCT registration number: **IRCT20200105046010N127**
Registration date: **2025-01-05, 1403/10/16**
Registration timing: **registered_while_recruiting**

Last update: **2025-05-09, 1404/02/19**
Update count: **1**

Registration date

2025-01-05, 1403/10/16

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

2024-12-21, 1403/10/01

Expected recruitment end date

2025-11-22, 1404/09/01

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Bioequivalence study of the intravenous solution of Ferric carboxy maltose 50mg/ml (Ferririse)manufactured by Zistdaru Danesh versus originator brand (Ferinject) in healthy volunteers in the fasted condition

Public title

Bioequivalence study of the intravenous solution of Ferric carboxy maltose

Purpose

Treatment

Inclusion/Exclusion criteria

Inclusion criteria:

Weight over 50 kg Informed consent Age (18-55 years old)

Exclusion criteria:

Pregnancy and breastfeeding History of allergy to ferric carboxy maltose or similar drugs Patients with high blood pressure Blood loss in a way that leads to hemodynamic instability. Receiving intravenous iron in the last 3-6 months.

Age

From **18 years** old to **55 years** old

Gender

Both

Phase

Bioequivalence

Groups that have been masked

- Participant

Sample size

Target sample size: **50**

More than 1 sample in each individual

Number of samples in each individual: **12**

Blood sample

Randomization (investigator's opinion)

Randomized

Randomization description

People in the mentioned age group are invited to participate through the advertisement. People are then checked for health and eligible candidates are identified. Each candidate is assigned a number from 1 to 50. The rand function of Excel software was used for randomization. The first 25 no.s are considered as (first sequence: Zistdaru Danesh's medicine) and the second 25 no.s (second sequence: originator brand recipient). The volunteers don't have any information about taking the test or brand drug.

Blinding (investigator's opinion)

Single blinded

Blinding description

This study is a single-blinded clinical trial (volunteers). The label of Zistdaru Danesh and the original brand are removed from the vials by the executor and the coded label is installed on it. Candidates don't know about receiving the type of brand medicine or test.

Placebo

Not used

Assignment

Parallel

Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee

Tabriz University of Medical Sciences Ethics Committee

Street address

International Relations Office, No 2 Central Building, Tabriz University of Medical Sciences, Golgasht Street,

City

Tabriz

Province

East Azarbaijan

Postal code

5165665931

Approval date

2024-12-02, 1403/09/12

Ethics committee reference number

IR.TBZMED.REC.1403.780

Health conditions studied

1

Description of health condition studied

This study is conducted on healthy volunteers.

ICD-10 code

ICD-10 code description

Primary outcomes

1

Description

Plasma concentration of the drug

Timepoint

Before, 0.5, 0.45, 1, 2, 4, 6, 12, 24, 36, 48 and 72h after drug administration

Method of measurement

Liquid Chromatography Mass-Mass

Secondary outcomes

1

Description

Time to reach maximum plasma concentration

Timepoint

After intervention

Method of measurement

Time to reach the maximum drug concentration in plasma 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 1: injection solution of ferric carboxy maltose 50 mg/ml manufactured by Vifor Pharma company as a reference
Category
Treatment - Drugs

2

Description
Intervention group 2: injection solution of ferric carboxy maltose 50 mg/ml manufactured by Zistdaru Danesh company as a test.
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, Moalem st., Abureihan St
City
Tabriz
Province
East Azarbaijan
Postal code
5154995671
Phone
+98 914 313 5843
Fax
Email
shokri.j@gmail.com

Sponsors / Funding sources

1

Sponsor
Name of organization / entity
Zistdaru danesh Co.
Full name of responsible person
Hooshmand Ilka
Street address
No. 404, 4th floor, Rose mall complex, Kharazi highway
City
Tehran
Province
Tehran
Postal code
1498711347
Phone
+98 21 4231 8100
Email
ilka@Zistdaru.com
Grant name
Grant code / Reference number
Is the source of funding the same sponsor organization/entity?
Yes
Title of funding source
Zistdaru danesh 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
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
Street address
No 4, 10th Ave., Boostan Street, Roshdieh
City
Tabriz
Province
East Azarbaijan
Postal code
5155935357
Phone
+98 41 3661 4125
Fax
Email
shokri.j@gmail.com

Person responsible for scientific 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

Street address
No 4, 10th Ave., Boostan Street, Roshdieh

City
Tabriz

Province
East Azarbaijan

Postal code
5166414766

Phone
+98 41 3334 8489

Email
shokri.j@gmail.com

Person responsible for updating data

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

Street address
No 4, 10th Ave., Boostan Street, Roshdieh

City
Tabriz

Province
East Azarbaijan

Postal code
5155935357

Phone
+98 41 3661 4125

Fax

Email
shokri.j@gmail.com

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