Clinical Trial Protocol
Iranian Registry of Clinical Trials

16 Sep 2026

Comparative bioequivalence study of the Omeprazole 10-mg Sachet manufactured by Nafas Zist Pharmed Pharmaceutical Company

Protocol summary

Study aim
Examining the equivalency of domestically produced tablet formulations with brand samples

Design
Cross-over unblinded randomization

Settings and conduct
The number of 24 healthy volunteers in the age range of 18-60 years and the weight range of 18 < BMI < 30, male, who are randomly and voluntarily selected through public notification. 1 tablet is taken fasting and blood is taken at 15 time points. A week later, the process is repeated for the external medicine

Participants/Inclusion and exclusion criteria
The weight range of participating candidates should be between 60-100 kg All candidates must be non-smokers Candidates should be healthy in terms of physical examination, ECG and the following laboratory tests: Hemoglobin, Hematocrit, Red and White Blood Count, MCV (Mean Body Volume), MCH (Mean Body Hemoglobin), Routine Urinalysis, Total Cholesterol, Triglyceride, Total Proteins, albumin, uric acid, total bilirubin, alkaline phosphatase, gamma glutamyl transpeptidase (γ-GT), aspartate aminotransferase (AST), alanine aminotransferase (ALT), urea, creatinine and fasting blood glucose Volunteers who have agreed to an informed consent form

Intervention groups
After taking a pill for internal production, 3 milliliters of blood will be collected from the volunteer in 15 time intervals for 12 hours. A week later, the process is repeated for a brand sample pill. The drug concentration is measured in plasma

Main outcome variables
Studying the Drug pharmacokinetic parameters

General information

Reason for update

Acronym

IRCT registration information
IRCT registration number: **IRCT20130313012810N9**
Registration date: **2023-05-08, 1402/02/18**
Registration timing: **retrospective**

Last update: **2023-05-08, 1402/02/18**
Update count: **0**

Registration date
2023-05-08, 1402/02/18

Registrant information

Name
Hamed Hamishehkar

Name of organization / entity
Drug Applied Research Center, Tabriz University of Medical Sciences

Country
Iran (Islamic Republic of)

Phone
+98 41 1336 3311

Email address
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Recruitment status
Recruitment complete

Funding source

Expected recruitment start date
2023-04-15, 1402/01/26

Expected recruitment end date
2023-04-25, 1402/02/05

Actual recruitment start date
empty

Actual recruitment end date
empty

Trial completion date
empty

Scientific title
Comparative bioequivalence study of the Omeprazole 10-mg Sachet manufactured by Nafas Zist Pharmed

Pharmaceutical Company

Public title
Comparative bioequivalence study of the Omeprazole 10-mg Sachet manufactured by Nafas Zist Pharmed Pharmaceutical Company
Purpose
Other
Inclusion/Exclusion criteria
Inclusion criteria:
The weight range of participating candidates should be between 60-100 kg All candidates must be non-smokers Candidates should be healthy in terms of physical examination, ECG and the following laboratory tests: Hemoglobin, Hematocrit, Red and White Blood Count, MCV (Mean Body Volume), MCH (Mean Body Hemoglobin), Routine Urinalysis, Total Cholesterol, Triglyceride, Total Proteins, albumin, uric acid, total bilirubin, alkaline phosphatase, gamma glutamyl transpeptidase (γ-GT), aspartate aminotransferase (AST), alanine aminotransferase (ALT), urea, creatinine and fasting blood glucose Volunteers who have agreed to an informed consent form All candidates should not consume caffeine-containing drinks and chocolate during two days before the prescription, and this restriction must be followed until the last blood draw
Exclusion criteria:
History of allergic or adverse reaction to Esomeprazole or any similar product Volunteers with blood pressure less than 60/90 mm Hg or higher than 90/140 mm Hg Individuals who donated whole blood or blood components within 2 months within 2 weeks prior to the first dose of the study product(s) Patients with neutrophil count less than 500 cells/mm3 Patients with lymphocyte count less than 500 cells/mm3 Patients with serious infection (e.g., sepsis) or active infection, including local infection
Age
From **18 years** old to **60 years** old
Gender
Male

Phase
Bioequivalence
Groups that have been masked
No information
Sample size
Target sample size: **24**
Randomization (investigator's opinion)
N/A
Randomization description
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 Tabriz University of Medical Sciences
Street address
Daneshghah St. Drug Applied Research Center
City
Tabriz
Province
East Azarbaijan
Postal code
5165665811
Approval date
2023-04-17, 1402/01/28
Ethics committee reference number
IR.TBZMED.REC.1402.088

Health conditions studied

1

Description of health condition studied
-
ICD-10 code
ICD-10 code description

Primary outcomes

1

Description
Plasma concentration of the drug
Timepoint
15 sampling time till 12 h
Method of measurement
Liquid Chromatography with tandem mass spectrometry (LC-MS-MS)

Secondary outcomes

empty

Intervention groups

1

Description
Intervention group: Intervention group: Intervention group: This study examines the bioequivalence of Esomeprazole tablets produced by a domestic company with a foreign brand sample. We have only one intervention group and there is no control group. The intervention group, which includes healthy, fasting male volunteers, will receive a single dose, a 100 mg tablet manufactured by the pharmaceutical company Nafas Zist Pharmed and AstraZeneca brand, in two 12-hour periods with an interval of one week, on the day of the study. And in 15 different time periods up to 12 hours after

taking the medicine, blood samples will be taken from the volunteers in the amount of 3 ml each time, that is, a total of 45 ml within 12 hours. The training that will be given to the volunteers includes avoiding the consumption of drinks containing alcohol and xanthine and other interfering drugs in the prescription drug from 48 hours before the start of the study until the end of the study.

Category
N/A

Recruitment centers

1

Recruitment center

Name of recruitment center
Drug Applied Research Center, Tabriz University of Medical Sciences

Full name of responsible person
Hamed Hamishehkar

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Sponsors / Funding sources

1

Sponsor

Name of organization / entity
Nafas Zist Pharmed Pharmaceutical Company

Full name of responsible person
Mehdi Rouhi Razlighi

Street address
No. 6, Unit 5, Sattar Khan, Shadi Alley, Tehran

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1441675816

Phone
+98 21 9200 1520

Email
info@nafaspharmed.com

Grant name

Grant code / Reference number

Is the source of funding the same sponsor organization/entity?
No

Title of funding source
Nafas Zist Pharmed

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
Hamed Hamishehkar

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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Hamed Hamishehkar

Position
professor

Latest degree
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Other areas of specialty/work
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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
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