

Clinical Trial Protocol

Iranian Registry of Clinical Trials

25 Jun 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 $18 < \text{BMI} < 30$, 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

hamishehkar.hamed@gmail.com

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

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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**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 updating data

Contact

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Other areas of specialty/work
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Medical Sciences
City

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