Clinical Trial Protocol
Iranian Registry of Clinical Trials

09 Nov 2026

In-vivo bioequivalence study of Esomeprazole 20 mg – Naproxen 500 mg tablet of the test drug manufactured by Actoverco pharmacutical company in compared with the reference drug Vimovo 20-500 mg tablet

Protocol summary

Study aim

In-vivo bioequivalence study of Esomeprazole 20 mg – Naproxen 500 mg tablet manufactured by Actoverco pharmacutical company in compared with the reference drug Vimovo 20-500 mg tablet

Design

Bioequivalence study, Cross-over design, Single dose, Single-blinded, 24 healthy volunteers, Two period, two week wash out period, Simple randomization method will be used.

Settings and conduct

This single-blind, two-period crossover study is conducted on two groups of healthy volunteers at Radin Shimi Company in Tabriz. Each period lasted 72 hours, with a two -week washout interval between them. In the first period, based on computer-generated randomization, Group 1 received the reference drug while Group 2 received the test drug. In the second period, the treatments were switched. The study is single-blind in which participants are unaware whether they receive the test or reference drug during either sampling period.

Participants/Inclusion and exclusion criteria

Inclusion criteria: the ages and BMIs of participant should be in the range of 18-55 and 18-30 respectively.
Exclusion criteria: Smoking, Alcohol and drug addiction, History of allergy to drug, Pregnancy.

Intervention groups

Intervention group 1 receives Esomeprazole 20 mg–Naproxen 500 mg tablet of the test drug manufactured by Actoverco pharmacutical company in the first round, and in the second round, after two-week washout period, the drug Vimovo 20-500 mg tablet .
Intervention group 2 receives the drugs in the switched order.

Main outcome variables

The concentration of the drug in blood, Time to reach maximum blood concentration, Extent of absorption

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20240804062647N40**
Registration date: **2026-06-06, 1405/03/16**
Registration timing: **prospective**

Last update: **2026-06-06, 1405/03/16**
Update count: **0**

Registration date

2026-06-06, 1405/03/16

Registrant information

Name

Massoud Amanlou

Name of organization / entity

Country

Iran (Islamic Republic of)

Phone

+98 21 6695 9067

Email address

amanlou@tums.ac.ir

Recruitment status

recruiting

Funding source

Expected recruitment start date

2026-07-06, 1405/04/15

Expected recruitment end date

2027-07-06, 1406/04/15

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date
empty

Scientific title
In-vivo bioequivalence study of Esomeprazole 20 mg – Naproxen 500 mg tablet of the test drug manufactured by Actoverco pharmacutical company in compared with the reference drug Vimovo 20-500 mg tablet

Public title
In-vivo bioequivalence of Esomeprazole 20 mg – Naproxen 500 mg tablet manufactured by Actoverco pharmacutical company

Purpose
Treatment

Inclusion/Exclusion criteria
Inclusion criteria:
Informed consent form Body mass index range (18-30) Age between18-55
Exclusion criteria:
Smoking Having a history of cardiovascular disease Having a history of liver & kidney disease Having a Alcohol & Drug addiction Having a hypersensitivity to the drug Pregnancy

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
At first, all of the volunteers are evaluated for meeting inclusion criteria, selecting the final participants. Each volunteer is randomly assigned to a number between 1 and 24 using simple randomization, receiving an identification card containing the assigned number. Next, at first study period, volunteers with even numbers will receive the reference drug and volunteers with odd numbers will receive the test drug. In the second period, the formulations are switched in a cross-over design.

Blinding (investigator's opinion)
Single blinded

Blinding description
This study is a single-blind (participant) clinical trialEsomeprazole 20 mg – Naproxen 500 mg tablet of the test drug manufactured by Actoverco pharmacutical company and the original brand are removed from their packaging by the operator and placed in identical, coded cans. Volunteers are unaware of the type of drug or test they are receiving.

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
Vice-Chancellery for Research and Technology, 3rd Floor, Central Building No. 2, Tabriz University of Medical Sciences, Golgasht Street
City
Tabriz
Province
East Azarbaijan
Postal code
5174864471

Approval date
2026-05-11, 1405/02/21

Ethics committee reference number
IR.TBZMED.REC.1405.100

Health conditions studied

1

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

ICD-10 code

ICD-10 code description

Primary outcomes

1

Description
The concentration of the drug in blood

Timepoint
0, 0.5, 1, 1.5, 2, 2.5, 3, 3.5, 4, 4.5, 5, 5.5, 6, 8, 10, 12, 24, 48, 72h after drug

Method of measurement
Liquid Chromatography with Mass-Mass Detector

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. This is done after completing the device analysis of the samples and through the WinNonLine software developed by Phoenix Company.

2

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

Intervention groups

1

Description
First intervention group: single dose of Esomeprazole 20 mg – Naproxen 500 mg tablet of the test drug manufactured by Actoverco pharmacutical company , in the first period. Cross-over design with two week wash out period.After two week in the second period, a single dose of Vimovo 20-500 mg
Category
Treatment - Drugs

2

Description
Second intervention group: Single-dose of Vimovo 20-500 mg , in the first period. Cross-over design with two week wash out period.After two week in the second period, a single dose of Esomeprazole 20 mg – Naproxen 500 mg tablet of the test drug manufactured by Actoverco pharmacutical company
Category
Treatment - Drugs

Recruitment centers

1

Recruitment center
Name of recruitment center
Radin laboratory
Full name of responsible person
Bahram Ataii
Street address
No.22, first floor, Moalem st., Abureihan St
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Tabriz
Province
East Azarbaijan
Postal code
5154995671
Phone
+98 914 311 5717
Email
ataii.bahram@gmail.com

Sponsors / Funding sources

1

Sponsor
Name of organization / entity
Actoverco Pharmaceutical Company
Full name of responsible person
Reza Karimi Mostofi
Street address
No58, Eighth Street, Nasr Alley,Tehran
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Province
Tehran
Postal code
1998678111
Phone
+98 21 4163 7000
Email
INFO@ACTOVERCO.COM
Grant name
Grant code / Reference number
Is the source of funding the same sponsor organization/entity?
Yes
Title of funding source
Actoverco Pharmaceutical Company
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
Other

Person responsible for general inquiries

Contact
Name of organization / entity
Tehran University of Medical Sciences
Full name of responsible person
Massoud Amanlou
Position
Academic staff and full-time professor of the Faculty of Pharmacy
Latest degree
Ph.D.
Other areas of specialty/work
Medical Pharmacy
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Position
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Person responsible for updating data

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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