Clinical Trial Protocol
Iranian Registry of Clinical Trials

25 Jun 2026

Bioequivalance study of esomeprazol 40 mg capsules manufactured by sina pishgam daru novin pharmaceutical company on 24 healthy volunteers and comparing pharmacokinetics results with Nexium 40 capsules manufactured by AstraZeneca

Protocol summary

Study aim
Comparing pharmacokinetics parameters of Sina pishgam daru novin Esomeprazole 40mg capsules and Nexium 40 mg Capsule of AstraZeneca company.

Design
Bioequivalance study insist of one 24 healthy volunteers group. This group itself randomly divided to two 12 volunteers sub-groups. The first sub-group administered reference drug and the second sub-groups administered generic or test drugs. The bioequivalance study is performed as cross over double blind within 1-2 weeks.

Settings and conduct
Bioequivalance Esomeprazole 40mg study will be performed under physician since 7 AM until 5 PM. This study is carried out as a cross over double blind investigation. The blind person included volunteers, administrator and analyst.

Participants/Inclusion and exclusion criteria
Acceptance criteria: Healthy liver and kidney and observing BMI limits Rejection criteria: Smokers and pregnancy

Intervention groups
Intervention group insist Measuring maximum plasma concentration and Tmax concentration.Control group include the volunteers administrated reference drugs and Measuring maximum plasma concentration and Tmax concentration.

Main outcome variables
Most important outcome is plasma concentration versus time profile. Pharmacokinetics parameters are calculated using this profile and included Cmax, Tmax, AUC0-t, AUC0-inf

General information

Reason for update

Acronym

IRCT registration information
IRCT registration number: **IRCT20200513047423N3**
Registration date: **2021-11-09, 1400/08/18**
Registration timing: **prospective**

Last update: **2021-11-09, 1400/08/18**
Update count: **0**

Registration date
2021-11-09, 1400/08/18

Registrant information

Name
Amir Mehdizadeh

Name of organization / entity
Ofogh pajo

Country
Iran (Islamic Republic of)

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+98 21 6673 8727

Email address
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Recruitment status
Recruitment complete

Funding source

Expected recruitment start date
2021-12-31, 1400/10/10

Expected recruitment end date
2022-01-21, 1400/11/01

Actual recruitment start date
empty

Actual recruitment end date
empty

Trial completion date
empty

Scientific title
Bioequivalance study of esomeprazol 40 mg capsules manufactured by sina pishgam daru novin pharmaceutical company on 24 healthy volunteers and comparing pharmacokinetics results with Nexium 40 capsules manufactured by AstraZeneca

Public title
Bio equivalence study of Esomeprazole 40 mg

Purpose
Other

Inclusion/Exclusion criteria

Inclusion criteria:
Healthy liver Healthy Kidney Observing BMI

Exclusion criteria:
Out of age ranges smoking Unhealthy liver and kidney Pregnancy

Age
From **18 years** old to **50 years** old

Gender
Both

Phase
Bioequivalence

Groups that have been masked

- Participant
- Data analyser

Sample size
Target sample size: **24**
More than 1 sample in each individual
Number of samples in each individual: **1**
Each volunteer has been administered once reference drug and the next time test drugs.

Randomization (investigator's opinion)
Randomized

Randomization description
We designate to 24 healthy volunteers one number between 1 and 24. Extraction of 12 numbers is carried out using random number table available in internet. these first 12 numbers establish first group.

Blinding (investigator's opinion)
Double blinded

Blinding description
The main investigator creates a table using randomization and divides 24 healthy volunteer in 2 groups which only he knows the details of group. Test and reference drugs are packaged in special envelopes that administrator and volunteers are blinded regarding to the kind of drugs. Volunteers, administrator (health care professional) and analyst are blinded regarding to reference and test drugs.

Placebo
Not used

Assignment
Crossover

Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee
Ethics committee of school of pharmacy and Nurcing &midwiferi-shahid beheshti univercity of medica

Street address
No.65, Razi Ave, Enghelab sq

City
Tehran

Province
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Postal code
1133713144

Approval date
2021-09-19, 1400/06/28

Ethics committee reference number
IR.SBMU.RETECH.REC.1400.410

Health conditions studied

1

Description of health condition studied
Bio equivalence Esomeprazole 40 mg

ICD-10 code

ICD-10 code description

Primary outcomes

1

Description
Increasing plasma concentration after administration of esomeprazole capsules till Tmax and then decreasing plasma concentration after Tmax

Timepoint
Initial blood sampling is performed before drug administration to obtain blank plasma chromatogram of each healthy volunteers.Hence the Tmax of esomeprazole is between 1.5 and 2.5 hours, so it is needed to have 5 blood samplings before Tmax. This period of time is called absorption phase.In the elimination phase (after Tmax)blood sampling carry out each hours.

Method of measurement
In this study, the variable is plasma concentration of esomeprazole. High performance liquid chromatography is used to determine the concentration of esomeprazole in plasma.

Secondary outcomes

empty

Intervention groups

1

Description
Intervention group 1: One esomeprazole 40 mg capsule manufactured by sina pishgam daru novin company(Test drug) is administrated to each of 12 healthy volunteers of group 1.
Category
Treatment - Drugs

2

Description
Intervention group 2: One Nexium 40 mg capsule manufactured by AstraZeneca company is administrated to each of 12 healthy volunteers of group 2.
Category
Treatment - Drugs

Recruitment centers

1

Recruitment center
Name of recruitment center
Ofoqh pharmed
Full name of responsible person
Dr Amir Mehdizadeh
Street address
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Sponsors / Funding sources

1

Sponsor
Name of organization / entity
Sina pishgam daru novin
Full name of responsible person
Dr Naser Arab
Street address
No 28, 4th alley, North Kargar Ave, Tehran
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1413694163
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Grant name
Grant code / Reference number
Is the source of funding the same sponsor organization/entity?
No
Title of funding source
Sina pishgam darou novin 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
Industry

Person responsible for general inquiries

Contact
Name of organization / entity
Ofogh pharmed labratory
Full name of responsible person
Dr Amir mehdizadeh
Position
Responsible pharmacist
Latest degree
Ph.D.
Other areas of specialty/work
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Person responsible for updating data

Contact

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Full name of responsible person

Amir Mehdizadeh

Position

Responsible pharmacist

Latest degree

Ph.D.

Other areas of specialty/work

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Sharing plan

Deidentified Individual Participant Data Set (IPD)

Yes - There is a plan to make this available

Study Protocol

Yes - There is a plan to make this available

Statistical Analysis Plan

Yes - There is a plan to make this available

Informed Consent Form

Yes - There is a plan to make this available

Clinical Study Report

Yes - There is a plan to make this available

Analytic Code

Undecided - It is not yet known if there will be a plan to make this available

Data Dictionary

Undecided - It is not yet known if there will be a plan to make this available

Title and more details about the data/document

Demography tables of volunteers including group 1 and 2 have been shared in bioequivalance report.

When the data will become available and for how long

The results of bioequivalance study of Esomeprazole capsules will be shared after accepting by Iranian food and drug organization.

To whom data/document is available

The results of bioequivalance study of Esomeprazole capsules will be accessed by expert by Iranian food and drug organization and financial supporter.

Under which criteria data/document could be used

To promotion of result of investigation, The results will be shared with eager.

From where data/document is obtainable

1- Iranian food and drug organization, 2- Ofogh pharmed research laboratory

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

To complied of educational filed of eager to result of investigation

Comments