# 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)

**Phone**
+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**
Tehran

**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**
No 65, Razi Ave, Enghelab Ave
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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
**City**
tehran
**Province**
Tehran
**Postal code**
1413694163
**Phone**
+98 21 8863 0175
**Email**
info@sinapishgamdarou.com

**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**
Medical Pharmacy
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## Person responsible for scientific inquiries

**Contact**
**Name of organization / entity**
Shahid Beheshti University of Medical Sciences
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Professor
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## Person responsible for updating data

**Contact**

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Ofogh pharmed

**Full name of responsible person**

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**Position**

Responsible pharmacist

**Latest degree**

Ph.D.

**Other areas of specialty/work**

Medical Pharmacy

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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**