Clinical Trial Protocol
Iranian Registry of Clinical Trials

10 Jun 2026

Bioequivalance study of Omeprazole 20mg capsules manufactured by Sina Pishgam Darou Novin pharmaceutical company on 24 healthy volunteers and comparing pharmacokinetics results with Omprazole capsules manufactured by Hexal

Protocol summary

Study aim
Comparing pharmacokinetics parameters of Sina Pishgam Darou Novin Omeprazole 20mg capsules and Omeprazole 20mg of HEXAL company.

Design
Bioequivalance study insists 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 Omeprazole 20mg 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 obseving BMI lmits 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: **IRCT20200513047423N2**
Registration date: **2021-10-07, 1400/07/15**
Registration timing: **prospective**

Last update: **2021-10-07, 1400/07/15**
Update count: **0**

Registration date
2021-10-07, 1400/07/15

Registrant information

Name
Amir Mehdizadeh

Name of organization / entity
Ofogh pajo

Country
Iran (Islamic Republic of)

Phone
+98 21 6673 8727

Email address
ofoghfarmed.lab@gmail.com

Recruitment status
Recruitment complete

Funding source

Expected recruitment start date
2021-10-08, 1400/07/16

Expected recruitment end date
2021-10-29, 1400/08/07

Actual recruitment start date
empty

Actual recruitment end date
empty

Trial completion date
empty

Scientific title
Bioequivalance study of Omeprazole 20mg capsules manufactured by Sina Pishgam Darou Novin pharmaceutical company on 24 healthy volunteers and comparing pharmacokinetics results with Omprazole capsules manufactured by Hexal

Public title
Bioequivalance study of Omeprazole 20mg
Purpose
Other
Inclusion/Exclusion criteria
Inclusion criteria:
Healthy liver Healthy kidney Observing BMI
Exclusion criteria:
Out of age ranges No smoker Unhealthy liver and kidney Pregnancy
Age
From **18 years** old to **50 years** old
Gender
Both

Phase
Bioequivalence
Groups that have been masked
No information
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 firs 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 and Nurcing & midwiferi-shahid beheshti univercity of medica
Street address
No.65, Razi Ave, Enghelab Ave
City
Tehran
Province
Tehran
Postal code
1133713144
Approval date
2021-09-19, 1400/06/28
Ethics committee reference number
IR.SBMU.RETECH.REC.1400.409

Health conditions studied

1

Description of health condition studied
Bioequivalance Omeprazole 20mg
ICD-10 code
ICD-10 code description

Primary outcomes

1

Description
Increasing plasma concentration after administration of Omeprazple 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 Omeprazole is between 1.5 and 2 hours, so it is needed to have 5 blood samplings before Tmax. This period of time is called absorption phase.
Method of measurement
In this study, the variable is plasma concentration of Omeprazole. High performance liquid chromatography is used to determine the concentration of Omeprazole in plasma.

Secondary outcomes

empty

Intervention groups

1

Description
Intervention group: OneOmeprazple capsule 20mg manufactured by Sina Pishgam Darou Novin (Test drug) is administrated to each of 12 healthy volunteers of group 1.

Category
Treatment - Drugs

2

Description
Intervention group: One Omeprazole 20mg capsule manufactured by HEXAL company is administrated to each of 12 healthy volunteers of group 2.
Category
Treatment - Drugs

Recruitment centers

1

Recruitment center
Name of recruitment center
Ofoq pharmed
Full name of responsible person
Dr Amir mehdizadeh
Street address
No.65, Razi Ave, Enghelab Ave
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a_mehdizadeh@gmail.com

Sponsors / Funding sources

1

Sponsor
Name of organization / entity
Sina Pishgam Darou 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
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 laboratory
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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Position
Professor
Latest degree
Ph.D.
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Person responsible for updating data

Contact

Name of organization / entity
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Full name of responsible person
Amir Mehdizadeh

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 Omeprazole capsules will be shared after accepting by Iranian food and drug organization.

To whom data/document is available
The results of bioequivalance study of Omeprazole capsules will be shared 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 laboratory

What processes are involved for a request to access data/document
To complide of educational filed of eager to result of investigation.

Comments