

Clinical Trial Protocol

Iranian Registry of Clinical Trials

09 Jun 2026

Bioequivalence 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

Bioequivalence study consists 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 bioequivalence study is performed as cross over double blind within 1-2 weeks.

Settings and conduct

Bioequivalence 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 observing BMI limits Rejection criteria: Smokers and pregnancy

Intervention groups

Intervention group consist Measuring maximum plasma concentration and Tmax concentration. Control group include the volunteers administered 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

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

Public title

Bioequivalence 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 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 and Nursing & midwifery-shahid beheshti university of medicine

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

Bioequivalence Omeprazole 20mg

ICD-10 code

ICD-10 code description

Primary outcomes

1

Description

Increasing plasma concentration after administration of Omeprazole capsules till T_{max} and then decreasing plasma concentration after T_{max}

Timepoint

Initial blood sampling is performed before drug administration to obtain blank plasma chromatogram of each healthy volunteers. Hence the T_{max} of Omeprazole is between 1.5 and 2 hours, so it is needed to have 5 blood samplings before T_{max}. 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: One Omeprazole capsule 20mg manufactured by Sina Pishgam Darou Novin (Test drug) is administered 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 administered to each of 12 healthy volunteers of group 2.

Category

Treatment - Drugs

Recruitment centers1**Recruitment center****Name of recruitment center**

Ofoq pharmed

Full name of responsible person

Dr Amir mehdizadeh

Street address

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Email

a_mehdizadeh@gmail.com

Sponsors / Funding sources1**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**

Ofoq 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

Full name of responsible person

Dr Farzad kobarfard

Position

Professor

Latest degree

Ph.D.

Other areas of specialty/work

Medical Pharmacy

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Person responsible for updating data**Contact****Name of organization / entity**

Ofoh pharmed

Full name of responsible person

Amir Mehdzadeh

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 bioequivalence report.

When the data will become available and for how long

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

To whom data/document is available

The results of bioequivalence 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-Ofoh pharmed laboratory

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

To complete of educational filed of eager to result of investigation.

Comments