

Clinical Trial Protocol

Iranian Registry of Clinical Trials

17 Sep 2026

Bioequivalence Study of Carvedilol 12.5 mg tablet manufactured by Shafa Pharmaceutical and Coreg manufactured by GSK in 24 Healthy Volunteers under fed condition

Protocol summary

Study aim

Bioequivalence study of Carvedilol tablets of Shafa Pharmaceutical company with Coreg tablets of GSK company (Germany)

Design

Bioequivalence study, Cross over, Double blinded, Random, in 24 healthy volunteers. Randomization was done by rand function of Excel software.

Settings and conduct

Sampling of volunteers is done in Kharazmi Plasma Center in Islamshahr. On the day of sampling, one 500 mg tablet of Carvedilol manufactured by Shafa or GSK on two occasions and with a washout period of 7 days, will be administered orally with 240 ml of water to the volunteers. For example, if in the first phase he received the medicine made by Shafa company, he will receive the brand medicine one week later. In each phase, 5 cc of blood sample will be taken before drug administration and at times 0, 0.33, 0.66, 1, 1.33, 1.66, 2, 2.5, 3, 3.5, 4, 5, 6, 8, 10, 24, 32 hours after prescribing the medicine . One week after the start of the study, the volunteer's cooperation in this research will be ended. The way to cooperate in this one week is that the drug is prescribed in the first day and after that 32 hours blood sampling is done at the mentioned times after washout period of one week the other drug is administered and blood samples will be taken at the same times.

Participants/Inclusion and exclusion criteria

Inclusion criteria: Healthy male or female volunteer between the ages of 18 and 55 with a body mass index (BMI) between 19 and 30 - People who are willing to sign an informed consent form. Exclusion criteria: history of heart disease. Systolic blood pressure less than 11 and diastolic less than 7 mmHg

Intervention groups

The first group: 12 people who take Shafa pharmaceutical tablets. The second group: 12 people

who take GSK pills on the same day.

Main outcome variables

Plasma concentration and area under the curve of plasma concentration time of test and reference drug

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20220209053979N10**

Registration date: **2023-06-18, 1402/03/28**

Registration timing: **prospective**

Last update: **2023-06-18, 1402/03/28**

Update count: **0**

Registration date

2023-06-18, 1402/03/28

Registrant information

Name

Roya Talari

Name of organization / entity

Country

Iran (Islamic Republic of)

Phone

+98 21 8880 0892

Email address

talari_r@yahoo.com

Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2023-06-30, 1402/04/09

Expected recruitment end date

2023-07-07, 1402/04/16

Actual recruitment start date

empty

Actual recruitment end date
empty

Trial completion date
empty

Scientific title
Bioequivalence Study of Carvedilol 12.5 mg tablet manufactured by Shafa Pharmaceutical and Coreg manufactured by GSK in 24 Healthy Volunteers under fed condition

Public title
Bioequivalence Study of Carvedilol 12.5 mg tablet manufactured by Shafa Pharmaceutical and Coreg manufactured by GSK

Purpose
Other

Inclusion/Exclusion criteria
Inclusion criteria:
Healthy male or female volunteers Body mass index (BMI) between 18 - 30 Volunteers who are willing to sign an informed consent form
Exclusion criteria:
Familial history of heart disease History of allergy to Carvedilol or formulation components History or significant clinical evidence of any disease Taking any type of medicine in the 14 days before the start of the study Participation in any clinical study within 30 days prior to study initiation Systolic blood pressure less than 11 and diastolic less than 7 mmHg

Age
From **18 years** old to **55 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: **17**
5 milliliter blood sample is taken from each volunteer

Randomization (investigator's opinion)
Randomized

Randomization description
Using the rand function of the Excel software, the candidates are divided into two groups, and half of them will receive numbers 1-12 and get the test drug, and the other half will receive numbers 13-24 and will take the reference drug.

Blinding (investigator's opinion)
Double blinded

Blinding description
The tablets of Shafa pharmaceutical and GSK are both oval shape and white, so the candidate does not know which company's drug he will receive in each phase of the study. Additionally, the tubes of the volunteers' samples are also coded, so the analyzer does not know

which company's drug he is analyzing, so only the researcher and the prescriber know which company's drug is being prescribed.

Placebo
Not used

Assignment
Crossover

Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee

Ethics Committee of Tehran University of Medical Science

Street address

Tehran University of Medical Science, 16 Azar St.,

City

Tehran

Province

Tehran

Postal code

1417713135

Approval date

2023-06-14, 1402/03/24

Ethics committee reference number

IR.TUMS.TIPS.REC.1402.040

Health conditions studied

1

Description of health condition studied

A crossover bioequivalence study in 24 healthy volunteers

ICD-10 code

ICD-10 code description

Primary outcomes

1

Description

Plasma concentration time profile, maximum plasma concentration, AUC

Timepoint

0, 0.33, 0.66, 1, 1.33, 1.66, 2, 2.5, 3, 3.5, 4, 5, 6, 8, 10, 24, 32 hours

Method of measurement

Liquid chromatography with mass spectrophotometry

Secondary outcomes

1

Description

Plasma concentration and then calculation of pharmacokinetic parameters like Cmax, AUC of test and reference drug.

Timepoint

0, 0.33, 0.66, 1, 1.33, 1.66, 2, 2.5, 3, 3.5, 4, 5, 6, 8, 10, 24, 32 hours

Method of measurement

Plasma concentration is measured by Liquid chromatography with mass spectrometry and pharmacokinetic parameters are calculated by excel.

Intervention groups

1

Description

Intervention group: Oral administration of one tablet of Carvedilol 12.5 mg manufactured by Shafa Company to 12 healthy volunteers with 240 ml of water half an hour after eating breakfast. Then 17 blood samples are taken from each volunteers at certain time.

Category

Treatment - Drugs

2

Description

Intervention group: Oral administration of one tablet of Coreg 12.5 mg manufactured by GSK Company to 12 healthy volunteers with 240 ml of water half an hour after eating breakfast. Then 17 blood samples are taken from each volunteers at certain time.

Category

Treatment - Drugs

Recruitment centers

1

Recruitment center

Name of recruitment center

Kharazmi plasma center

Full name of responsible person

Sara Solgi

Street address

No. 13, Shehamat 1st Alley, Ali Ibn Abitalib St., Namaz Square,

City

Islamshar

Province

Tehran

Postal code

3313679886

Phone

+98 21 5669 4726

Email

Info@kpcir.com

Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Shafa Pharmaceutical Company

Full name of responsible person

Dr.Razgardani

Street address

No. 13, Golberg Alley 4 East, Fakhar Moghadam St., Dadman St., Shahrek Gharb,

City

Tehran

Province

Tehran

Postal code

3197996423

Phone

+98 21 8836 8521

Email

info@shafadarou.org

Grant name

Grant code / Reference number

Is the source of funding the same sponsor organization/entity?

Yes

Title of funding source

Shafa 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

Industry

Person responsible for general inquiries

Contact

Name of organization / entity

Kharazmi Plasma Center

Full name of responsible person

Roya Talari

Position

Excuter

Latest degree

Ph.D.

Other areas of specialty/work

Medical Pharmacy

Street address

No. 13, Shehamat 1st Alley, Ali Ibn Abitalib St., Namaz Square,

City

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Phone

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Email

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Person responsible for scientific inquiries

Contact

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Kharazmi Plasma Center

Full name of responsible person

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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

The bioequivalence study data is completely confidential and according to the contract with Pharmachemi Company, it should not be published anywhere.

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