# 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 spectrometery and pharmacokientic 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,
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talari_r@yahoo.com

## Person responsible for scientific inquiries

**Contact**

**Name of organization / entity**

Kharazmi Plasma Center

**Full name of responsible person**

Roya Talari

**Position**

Excruter

**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**

Kharazmi Plasma Center

**Full name of responsible person**

Roya Talari

**Position**

Executer

**Latest degree**

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**Other areas of specialty/work**

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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