

Clinical Trial Protocol

Iranian Registry of Clinical Trials

09 Jun 2026

Single-dose bioequivalence studies of Gemifloxacin tablets (320 mg) in healthy volunteers

Protocol summary

Study aim

Administration of test (generic) and reference (brand) products to healthy subjects Comparison of bioavailability and pharmacokinetics of two products Evaluation of interchangeability of two products

Design

This clinical trial study with control group was conducted on 26 patients with parallel, double-blind, random allocation, and bio-equivalence phase. 26 healthy volunteers after passing the inclusion and exclusion criteria will be divided into two groups of test and reference. Then, in the second period, the group that received the test drug will receive the reference drug and the other group will receive the test drug.

Settings and conduct

This study was single-dose, randomized, and crossover. In this way, after completing the consent form and being aware of the drug and its side effects, the candidates consume the test product in one period and the reference product in the other period. This study was conducted at Shahid Beheshti School of Pharmacy.

Participants/Inclusion and exclusion criteria

Inclusion criteria: Healthy volunteers aged 18 to 50 years
Exclusion criteria: History of liver, kidney and cardiovascular diseases that can affect drug clearance from body History of taking any medication in the last two weeks Creatinine above 2

Intervention groups

Receiving test product Receiving reference product

Main outcome variables

The variables of this study include the maximum plasma concentration of the drug, the time to reach the maximum plasma concentration of the drug and the area below the concentration versus time curve. The first two variables are a measure of drug uptake rate and the third variable is a measure of drug uptake.

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20210201050197N3**

Registration date: **2021-03-08, 1399/12/18**

Registration timing: **retrospective**

Last update: **2021-03-08, 1399/12/18**

Update count: **0**

Registration date

2021-03-08, 1399/12/18

Registrant information

Name

Azadeh Haeri

Name of organization / entity

Country

Iran (Islamic Republic of)

Phone

+98 21 8820 0212

Email address

a_haeri@sbmu.ac.ir

Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2021-02-04, 1399/11/16

Expected recruitment end date

2021-03-02, 1399/12/12

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Single-dose bioequivalence studies of Gemifloxacin tablets (320 mg) in healthy volunteers

Public title

Bioequivalence of Gemifloxacin

Purpose

Other

Inclusion/Exclusion criteria

Inclusion criteria:

Healthy volunteer Age: 18-50 year

Exclusion criteria:

History of liver, kidney and cardiovascular diseases that can affect drug clearance from body History of taking any medication in the last two weeks Creatinine above 2

Age

From **18 years** old to **50 years** old

Gender

Male

Phase

Bioequivalence

Groups that have been masked

- Participant
- Care provider

Sample size

Target sample size: **26**

Randomization (investigator's opinion)

Randomized

Randomization description

In order to allocate randomly in this study, the simple and limited random allocation rule will be used. This method represents a large block for the total sample size, which means that the balance in the number of people assigned to each group will be achieved at the end. For this purpose, 26 candidates who meet the inclusion criteria will be selected first. Then, 13 lots for the intervention group and 13 lots for the control group are placed in a lottery container. Then, each of these 26 people randomly removes a lottery ticket from the container without replacement and deliver the lottery to the person in charge of the project and the group allocation to the individual is determined (the individual, the doctor, and the responsible nurse are not aware of the group allocation to the individual). In the second phase of the study, the individual in the control group is transferred to the intervention group and vice versa.

Blinding (investigator's opinion)

Double blinded

Blinding description

Candidates receive medication twice. Once Iranian product (generic) and once the foreign product (reference). Volunteers and study physicians are not aware of what products they have received at every turn. Because the medicine is taken out of its box and blister and given to the volunteers, they will have no knowledge of the type of medicine. The new drug is made in terms of color, smell, taste, consistency, and all appearance characteristics similar to the reference drug so that the participants are blind in this regard.

Placebo

Not used

Assignment

Crossover

Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee

School of Pharmacy Nursing and Midwifery, Shahid Beheshti Medical University

Street address

No 2660, School of Pharmacy Nursing and Midwifery, Shahid Beheshti Medical University, Niayesh building, Valiasr Ave

City

Tehran

Province

Tehran

Postal code

1996835113

Approval date

2020-05-31, 1399/03/11

Ethics committee reference number

IR.SBMU.PHARMACY.REC.1399.045

Health conditions studied

1

Description of health condition studied

Healthy subjects

ICD-10 code

ICD-10 code description

Primary outcomes

1

Description

Plasma drug concentration

Timepoint

20, 40 Mins, 1,1.5, 2, 3, 4, 6, 8, 10, 12, 14, 24 Hours

Method of measurement

High performance liquid chromatography (HPLC) method

Secondary outcomes

empty

Intervention groups

1

Description

Intervention group: Receiving Iranian medicine (generic product): In this group, each volunteer receives a 320 mg gemifloxacin tablets made by Aria Company during a

treatment period. After that, blood samples are taken from the volunteers for 24 hours. Blood samples (5 cc) are taken from volunteers at different times (14 times). This completes a course of study. Pharmacokinetic parameters are calculated and compared by determining the drug concentration in blood samples by High-performance liquid chromatography (HPLC).

Category

Treatment - Drugs

2**Description**

Control group: Receiving reference medicine: In this group, each volunteer receives one reference tablet of 320 mg Gemifloxacin in a course of treatment. After that, blood samples are taken from the volunteers for 24 hours. Blood samples (5 cc) are taken from volunteers at different times (14 times). This completes a course of study. Pharmacokinetic parameters are calculated and compared by determining the drug concentration in blood samples by HPLC.

Category

Treatment - Drugs

Recruitment centers**1****Recruitment center****Name of recruitment center**

School of Pharmacy, Shahid Beheshti University of Medical Sciences

Full name of responsible person

Azadeh Haeri

Street address

No 2660, School of Pharmacy Nursing and Midwifery, Shahid Beheshti Medical University, Niayesh building, Valiasr Ave

City

Tehran

Province

Tehran

Postal code

1996835113

Phone

+98 21 8820 0212

Email

a_haeri@sbmu.ac.ir

Sponsors / Funding sources**1****Sponsor****Name of organization / entity**

Arya Pharmaceutical Company

Full name of responsible person

Rahim Shabestari

Street address

Tehran Karaj Highway, Kilometer 17

City

Tehran

Province

Tehran

Postal code

1397133111

Phone

+98 21 4498 1081

Email

info@aryapharm.com

Grant name**Grant code / Reference number****Is the source of funding the same sponsor organization/entity?**

Yes

Title of funding source

Arya 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**

Shahid Beheshti University of Medical Sciences

Full name of responsible person

Azadeh Haeri

Position

Assistant professor

Latest degree

Ph.D.

Other areas of specialty/work

Medical Pharmacy

Street address

No 2660, School of Pharmacy Nursing and Midwifery, Shahid Beheshti Medical University, Niayesh building, Valiasr Ave

City

Tehran

Province

Tehran

Postal code

1996835113

Phone

+98 21 8820 0212

Email

a_haeri@sbmu.ac.ir

Person responsible for scientific inquiries**Contact****Name of organization / entity**

Shahid Beheshti University of Medical Sciences

Full name of responsible person

Azadeh Haeri

Position

Assistant professor

Latest degree

Ph.D.

Other areas of specialty/work

Medical Pharmacy

Street address

No 2660, School of Pharmacy Nursing and Midwifery,
Shahid Beheshti Medical University, Niayesh building,
Valiasr Ave

City

Tehran

Province

Tehran

Postal code

1996835113

Phone

+98 21 8820 0212

Email

a_haeri@sbmu.ac.ir

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

Shahid Beheshti University of Medical Sciences

Full name of responsible person

Azadeh Haeri

Position

Assistant professor

Latest degree

Ph.D.

Other areas of specialty/work

Medical Pharmacy

Street address

No 2660, School of Pharmacy Nursing and Midwifery,
Shahid Beheshti Medical University, Niayesh building,
Valiasr Ave

City

Tehran

Province

Tehran

Postal code

1996835113

Phone

+98 21 8820 0212

Email

a_haeri@sbmu.ac.ir

Sharing plan**Deidentified Individual Participant Data Set (IPD)**

Undecided - It is not yet known if there will be a plan to make this available

Study Protocol

Undecided - It is not yet known if there will be a plan to make this available

Statistical Analysis Plan

Undecided - It is not yet known if there will be a plan to make this available

Informed Consent Form

No - There is not a plan to make this available

Clinical Study Report

Undecided - It is not yet known if there will be 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