

Clinical Trial Protocol

Iranian Registry of Clinical Trials

10 Jun 2026

Comparative bioequivalence study of Ciprofloxacin 500 mg Tablet of Dorsa Pharmaceutical Co. and Ciprobay 500 mg tablet of BAYER as reference in 24 healthy male under fasting.

Protocol summary

Study aim

This study will be performed to compare the pharmacokinetics and in vivo parameters of Ciprofloxacin 500 mg tablet formulation as a test product with Ciprobay 500 mg formulation as a reference product and to evaluate the bioequivalence of these two formulations.

Design

Non blinded, randomized, crossover in vivo bioequivalence study in 24 healthy male under fasting condition.

Settings and conduct

In each period, volunteers will receive a single dose intervention (1 or 2) in the Farabi Clinic (Eslamshahr, Tehran). 17 blood samples were collected during 72 hours post intervention. A 7-day washout interval separated to study periods.

Participants/Inclusion and exclusion criteria

Healthy subjects (male) between 20 - 45 years of age and Body Mass Index (BMI) within 15% of normal range between 18.5 - 30 kg/m². Subjects with no significant diseases or clinically significant abnormal findings during screening, medical history, clinical examination and laboratory evaluations. Previous history of allergy to a fluoroquinolone or severe allergic reaction to any medication. History of CNS disorders (e.g. convulsive seizures). History or presence of cardiovascular, respiratory, hepatic, renal, gastrointestinal, endocrine, hematological, neuromuscular, psychiatric, auto-immune or neurological disorders.

Intervention groups

Intervention group 1: Ciprofloxacin 500 mg tablet, produced by Dorsa pharmaceutical Co. is the test product. In each period, 12 of 24 subjects will be given a single oral dose of this product. Intervention group 2: Ciprobay 500 mg tablet, produced by BAYER is the reference product. In each period, 12 of 24 subjects will

be given a single oral dose of this product.

Main outcome variables

Peak Plasma Concentration

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20180620040164N31**

Registration date: **2022-07-05, 1401/04/14**

Registration timing: **prospective**

Last update: **2022-07-05, 1401/04/14**

Update count: **0**

Registration date

2022-07-05, 1401/04/14

Registrant information

Name

Behzad Montaha Sangari

Name of organization / entity

Noor research and educational institute (Tavan)

Country

Iran (Islamic Republic of)

Phone

+98 21 6600 7026

Email address

info@tavaninstitute.ir

Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2022-07-23, 1401/05/01

Expected recruitment end date

2022-08-06, 1401/05/15

Actual recruitment start date

empty

Actual recruitment end date
empty

Trial completion date
empty

Scientific title
Comparative bioequivalence study of Ciprofloxacin 500 mg Tablet of Dorsa Pharmaceutical Co. and Ciprofloxacin 500 mg tablet of BAYER as reference in 24 healthy male under fasting.

Public title
Comparative in vivo evaluation of 2 Ciprofloxacin 500 mg mg Tablet formulations.

Purpose
Treatment

Inclusion/Exclusion criteria
Inclusion criteria:
Healthy subjects (male) between 20 – 45 years of age and Body Mass Index (BMI) within 15% of normal range between 18.5 - 30 kg/m². Subjects with no significant diseases or clinically significant abnormal findings during screening, medical history, clinical examination and laboratory evaluations. Subjects that have normal vital signs. Subjects who agree with patient consent form.
Exclusion criteria:
Previous history of allergy to a fluoroquinolone or severe allergic reaction to any medication. History of CNS disorders (e.g. convulsive seizures). History or presence of cardiovascular, respiratory, hepatic, renal, gastrointestinal, endocrine, hematological, neuromuscular, psychiatric, auto-immune or neurological disorders. Smoking more than 10 cigarettes per day and could not tolerate cigarette cessation during each clinical period. Subjects who has used any drug including prescription or Over-The-Counter (OTC) drugs within 14 days prior to the start of the study and might need drug intake during study period. Heavy drinker of caffeine, grapefruit juice or caffeinated drinks or who are on special diet (such as vegetarians) or do exertional physical activity. A history of difficulty with donating blood or donation of more than 500 ml blood within 7 days prior to the start of the study.

Age
From **20 years** old to **45 years** old

Gender
Male

Phase
Bioequivalence

Groups that have been masked
No information

Sample size
Target sample size: **24**

Randomization (investigator's opinion)
Randomized

Randomization description
The randomization schedule will be generated with <https://www.sealedenvelope.com/simple-randomiser/v1/lis>. A 2*2 block randomization list is created. We have 12 blocks and within each two volunteer's number (allocated after screening) for all 24 volunteers.

According to this list, a treatment sequence of Test/Reference or Reference/Test will be given to each volunteer.

Blinding (investigator's opinion)
Not blinded

Blinding description
Placebo
Not used

Assignment
Crossover

Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee

Ethics Committee of School of Pharmacy and Nursing & Midwifery- Shahid Beheshti University of Medical Sciences

Street address

Niayesh Highway, Valiasr Ave, Tehran, Iran

City

Tehran

Province

Tehran

Postal code

1996835113

Approval date

2021-08-10, 1400/05/19

Ethics committee reference number

IR.SBMU.PHARMACY.REC.1400.113

Health conditions studied

1

Description of health condition studied

Bacterial infections

ICD-10 code

A49.8

ICD-10 code description

Other bacterial infections of unspecified site

Primary outcomes

1

Description

Peak Plasma Concentration (C_{max})

Timepoint

17 blood samples will be withdrawn pre-dose and at 0.5, 1, 1.5, 2, 2.5, 3, 3.5, 4, 5, 6, 8, 9, 10, 12, 24, 48 and 72 hours after intervention.

Method of measurement

Using non-compartmental model of Win-Nonlin Professional software version 3.2.A (Pharsight Corporation, USA)

Secondary outcomes

1

Description

AUC (Area Under the Concentration-Time Curve)

Timepoint

17 blood samples will be withdrawn pre-dose and at 0.5, 1, 1.5, 2, 2.5, 3, 3.5, 4, 5, 6, 8, 9, 10, 12, 24, 48 and 72 hours after intervention.

Method of measurement

Using non-compartmental model of Win-Nonlin Professional software version 3.2.A (Pharsight Corporation, USA)

Intervention groups

1

Description

Intervention group 1: Ciprofloxacin 500 mg Tablet, produced by Dorsa Pharmaceutical Co. is the test product. In each period, 12 of 24 subjects will be given single oral dose of this product. After 7-day wash-out period the intervention 2 will be given to these subjects.

Category

Treatment - Drugs

2

Description

Intervention group 2: Ciprofloxacin 500 mg tablet, produced by BAYER is the reference product. In each period, 12 of 24 subjects will be given single oral dose of this product. After 7-day wash-out period the intervention 1 will be given to these subjects.

Category

Treatment - Drugs

Recruitment centers

1

Recruitment center

Name of recruitment center

Hakim Farabi Clinic

Full name of responsible person

Ebrahim Siahpoosh

Street address

No. 57, Shemshad alley, in front of Sallor town

City

Tehran

Province

Tehran

Postal code

4635314588

Phone

+98 21 9253 5647

Email

partochem@gmail.com

Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Dorsa Pharmaceutical Co.

Full name of responsible person

Amir Esmael Saghafinia

Street address

8th floor; -Fanavari Tarasht Tower; Teimori; Shahid Salehi Blvd

City

Tehran

Province

Tehran

Postal code

1459965204

Phone

+98 21 5461 2000

Email

info@dorsadarou.com

Grant name

Grant code / Reference number

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

Yes

Title of funding source

Dorsa Pharmaceutical Co.

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

Noor Research & Development Institute

Full name of responsible person

Ali Aghaei

Position

Master

Latest degree

Master

Other areas of specialty/work

Pharmacy

Street address

Sharif innovation station, North Habibollah Street, Hosseini Square, Teymouri Street, Tarasht

City

Tehran

Province

Tehran

Postal code

1459926609

Phone

+98 21 6600 4027

Email

partochem@gmail.com

Person responsible for scientific inquiries

Contact

Name of organization / entity

Tavan Institute

Full name of responsible person

Seyed Mohsen Foroutan

Position

Principal investigator

Latest degree

Ph.D.

Other areas of specialty/work

Medical Pharmacy

Street address

Sharif innovation station, North Habibollah Street,
Hosseini Square, Teymoury Street, Tarasht.

City

Tehran

Province

Tehran

Postal code

1459926609

Phone

+98 21 6600 4027

Email

mforoutan@gmail.com

Person responsible for updating data

Contact

Name of organization / entity

Tavan Institute

Full name of responsible person

Ali Aghaei

Position

Master

Latest degree

Master

Other areas of specialty/work

Pharmacy

Street address

Sharif innovation station, North Habibollah Street,
Hosseini Square, Teymoury Street, Tarasht.

City

Tehran

Province

Tehran

Postal code

1459926609

Phone

+98 21 6600 4027

Email

partochem@gmail.com

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

It's undetermined yet.

Study Protocol

Undecided - It is not yet known if there will be 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