Clinical Trial Protocol
Iranian Registry of Clinical Trials

06 Jul 2026

Bioequivalence study of celecoxib 200 mg capsule of Mehr Darou pharmaceutical company compared to celecoxib 200 mg sample of Pfizer company in Germany on healthy volunteers

Protocol summary

Study aim

Bioequivalence study of celecoxib 200 mg capsule of Mehr Darou pharmaceutical company compared to celecoxib 200 mg sample of Pfizer company in Germany on healthy volunteers

Design

The present clinical trial includes the bioequivalence study of celecoxib 200 mg capsules of Mehr Daru pharmaceutical company compared to celecoxib 200 mg of Pfizer, Germany, after administration to 24 healthy human volunteers, as two interventions to one group, in a cross-over, blinded manner. It is not done and is not random.

Settings and conduct

The study is carried out at Nik Azma Pars Alborz company located in Mahdasht Karaj. The blinded cross-over study includes two phases (oral consumption of one 200 mg celecoxib capsule per study and 2 times in total) with a one-week washout period on 24 fasting healthy volunteers. Then the obtained blood samples are determined.

Participants/Inclusion and exclusion criteria

Inclusion criteria: healthy volunteers; between the ages of 18 and 55; non-smokers. Exclusion criteria: volunteers with blood pressure less than 90 over 60 mm Hg or higher than 140 over 90 mm Hg

Intervention groups

The study includes two stages in the form of intervention 1: including oral consumption of celecoxib 200 mg capsules of Mehr Daru pharmaceutical company in Iran and intervention 2: oral consumption of celecoxib 200 mg capsules of Pfizer in Germany. This study will be repeated on fasting volunteers in a cross-sectional manner with an interval of one week.

Main outcome variables

Maximum plasma concentration

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20230222057495N13**
Registration date: **2023-12-20, 1402/09/29**
Registration timing: **registered_while_recruiting**

Last update: **2023-12-20, 1402/09/29**
Update count: **0**

Registration date

2023-12-20, 1402/09/29

Registrant information

Name

Monireh Jalalipour

Name of organization / entity

Nikazma Pars Alborz company

Country

Iran (Islamic Republic of)

Phone

+98 26 3731 8748

Email address

info@naplab.ir

Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2023-12-16, 1402/09/25

Expected recruitment end date

2024-12-15, 1403/09/25

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title
Bioequivalence study of celecoxib 200 mg capsule of Mehr Darou pharmaceutical company compared to celecoxib 200 mg sample of Pfizer company in Germany on healthy volunteers

Public title
Bioequivalence study of celecoxib 200 mg capsule
Purpose
Other
Inclusion/Exclusion criteria
Inclusion criteria:
Healthy volunteer between 18 and 55 years old. Body mass index less than 30 kg per square meter. All candidates must be non-smokers.
Exclusion criteria:
Blood pressure less than 90 on 60 mm Hg or more than 140 on 90 mm Hg. Consumption of any drug, alcohol or tobacco within 2 weeks before receiving the drug
Age
From **18 years** old to **55 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: **30**

Randomization (investigator's opinion)
Not randomized
Randomization description
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
Research Institute of Pharmaceutical Sciences, Tehran University of Medical Sciences
Street address
Institute of Pharmaceutical Sciences, Faculty of Pharmacy, Tehran University of Medical Sciences, Porsina Street
City
Tehran
Province
Tehran
Postal code
1417613151
Approval date
2023-11-26, 1402/09/05
Ethics committee reference number
IR.TUMS.TIPS.REC.1402.112

Health conditions studied

1

Description of health condition studied

ICD-10 code
ICD-10 code description

Primary outcomes

1

Description
Maximum plasma concentration of celecoxib
Timepoint
Before taking the drug and: 0.5, 1, 1.5, 2, 2.5, 3, 3.5, 4, 5, 6, 8, 10, 24 and 48 hours after taking the drug
Method of measurement
Liquid chromatography-mass spectrometry

Secondary outcomes

empty

Intervention groups

1

Description
Intervention group 1: includes the oral intake of celecoxib 200 mg capsules of Mehr Daru pharmaceutical company in Iran on 24 healthy fasting volunteers. 5 ml of blood at time intervals before starting the medication and: 0.5, 1, 1.5, 2, 2.5, 3, 3.5, 4, 5, 6, 8, 10, 24 and 48 hours. After taking the medicine, it is taken from the volunteers. The cross-over study consists of two phases (oral consumption of one celecoxib 200 mg capsule per study and 2 times in total) with a one-week washout period (when the drug is completely removed from your blood). Celecoxib plasma concentration is determined by liquid chromatography-mass spectrometry method.
Category
Other

2

Description
Intervention group 2: Oral consumption of celecoxib 200 mg capsules from Pfizer, Germany on 24 healthy fasting volunteers. 5 ml of blood at time intervals before starting

the medication and: 0.5, 1, 1.5, 2, 2.5, 3, 3.5, 4, 5, 6, 8, 10, 24 and 48 hours. After taking the medicine, it is taken from the volunteers. The cross-over study consists of two phases (oral consumption of one celecoxib 200 mg capsule per study and 2 times in total) with a one-week washout period (when the drug is completely removed from your blood). Celecoxib plasma concentration is determined by liquid chromatography-mass spectrometry method.

Category
Other

Recruitment centers

1

Recruitment center

Name of recruitment center
Nik Azma Pars Alborz Laboratory

Full name of responsible person
Monireh Jalalipour

Street address
No. 419, Azadegan Square, Imam Khomeini Boulevard

City
Mahdasht Karaj

Province
Alborz

Postal code
3188913179

Phone
+98 26 3731 8748

Email
info@naplab.ir

Sponsors / Funding sources

1

Sponsor

Name of organization / entity
Mehr Darou Pharmaceutical Company

Full name of responsible person
Roxana Naeeli

Street address
No. 7, end of 23rd street, Km 10 of Tehran-Karaj special road

City
Tehran

Province
Tehran

Postal code
1399734137

Phone
+98 21 4454 3320

Email
info@mehrdarou.com

Grant name

Grant code / Reference number

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

Title of funding source
Mehr Darou 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
Nik Azma Pars Alborz laboratory

Full name of responsible person
Monireh Jalalipour

Position
Responsible Pharmacist

Latest degree
Ph.D.

Other areas of specialty/work
Medical Pharmacy

Street address
No. 419, Azadegan Square, Imam Khomeini Boulevard

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Person responsible for scientific inquiries

Contact

Name of organization / entity
Nik Azma Pars Alborz laboratory

Full name of responsible person
Monireh Jalalipour

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Person responsible for updating data

Contact

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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

Undecided - It is not yet known if there will be 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

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