

Clinical Trial Protocol

Iranian Registry of Clinical Trials

04 Jun 2026

Bioequivalence study of phenazopyridine hydrochloride 100 mg tablets of Mehr Darou pharmaceutical company compared to the phenazopyridine hydrochloride 100 mg sample of Pfizer in Germany on healthy volunteers.

Protocol summary

Study aim

Bioequivalence study of phenazopyridine hydrochloride 100 mg tablets of Mehr Darou pharmaceutical company compared to the phenazopyridine hydrochloride 100 mg sample of Pfizer in Germany on healthy volunteers.

Design

The present clinical trial includes the study of the bioequivalence of phenazopyridine hydrochloride 100 mg tablets of Mehr Darou pharmaceutical company compared to the phenazopyridine hydrochloride 100 mg sample of Pfizer, Germany, After administration to 24 healthy human volunteers, it is an intervention group, cross-over, unblinded and non-randomized.

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 100 mg phenazopyridine hydrochloride tablet 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

Entry criteria: healthy volunteers; Age between 18 and 55 years; non smoker
Non-entry criteria: candidates with blood pressure less than 90 on 60 mm Hg or higher than 140 on 90 mm Hg.

Intervention groups

The study includes two stages as intervention 1: including oral consumption of phenazopyridine hydrochloride 100 mg tablets of Mehr Darou pharmaceutical company in Iran and intervention 2: oral consumption of phenazopyridine hydrochloride 100 mg tablets of Pfizer company 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: **IRCT20230222057495N11**

Registration date: **2023-12-16, 1402/09/25**

Registration timing: **registered_while_recruiting**

Last update: **2023-12-16, 1402/09/25**

Update count: **0**

Registration date

2023-12-16, 1402/09/25

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 phenazopyridine hydrochloride 100 mg tablets of Mehr Darou pharmaceutical company compared to the phenazopyridine hydrochloride 100 mg sample of Pfizer in Germany on healthy volunteers.

Public title

Bioequivalence study of phenazopyridine hydrochloride 100 mg tablet

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: **28**

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

2023-12-10, 1402/09/19

Ethics committee reference number

IR.TUMS.TIPS.REC.1402.120

Health conditions studied

1

Description of health condition studied

ICD-10 code

ICD-10 code description

Primary outcomes

1

Description

The maximum plasma concentration of phenazopyridine hydrochloride

Timepoint

Before taking the drug and: 0.25, 0.5, 0.75, 1, 1.5, 2, 2.5, 3, 4, 6, 8, 10 and 24 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 consumption of 100 mg phenazopyridine hydrochloride tablets of Mehr Darou Pharmaceutical Company of Iran on 24 healthy fasting volunteers. 5 ml of blood at time intervals before starting the drug and: 0.25, 0.5, 0.75, 1, 1.5, 2, 2.5, 3, 4, 6, 8, 10 and 24 hours. After taking the medicine, it is taken from the volunteers. The cross-over study consists of two phases (oral consumption of one 100 mg phenazopyridine hydrochloride tablet per study and 2 times in total) with a one-week washout period (when the drug is completely removed from your blood). The plasma concentration of phenazopyridine hydrochloride is determined by liquid chromatography-mass spectrometry method.

Category

Other

2

Description

Intervention group 2: includes the oral consumption of 100 mg phenazopyridine hydrochloride tablets of Pfizer, Germany, on 24 fasting healthy volunteers. 5 ml of blood at time intervals before starting the drug and: 0.25, 0.5, 0.75, 1, 1.5, 2, 2.5, 3, 4, 6, 8, 10 and 24 hours. After taking the medicine, it is taken from the volunteers. The cross-over study consists of two phases (oral consumption of one 100 mg phenazopyridine hydrochloride tablet per study and 2 times in total) with a one-week washout period (when the drug is completely removed from your blood). The plasma concentration of phenazopyridine hydrochloride 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

City

Mahdasht Karaj

Province

Alborz

Postal code

3188913179

Phone

+98 26 3731 8748

Email

info@naplab.ir

Person responsible for scientific 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

City
Mahdasht Karaj
Province
Alborz
Postal code
3188913179
Phone
+98 26 3731 8748
Email
info@naplab.ir

Person responsible for updating data

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 Squar, Imam Khomeini Boulevard
City
Mahdasht Karaj
Province
Alborz

Postal code
3188913179
Phone
+98 26 3731 8748
Email
info@naplab.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

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