

Clinical Trial Protocol

Iranian Registry of Clinical Trials

09 Jun 2026

Bioequivalence study of mefenamic acid 500 mg tablets of Darou Darman Parmida pharmaceutical company compared to mefenamic acid 500 mg of Pfizer in Turkey on healthy volunteers.

Protocol summary

Study aim

Bioequivalence study of mefenamic acid 500 mg tablets of Darou Darman Parmida pharmaceutical company compared to mefenamic acid 500 mg of Pfizer company in Turkey on healthy volunteers.

Design

The present clinical trial includes the study of the bioequivalence of mefenamic acid 500 mg tablets produced by Darou Darman Parmida pharmaceutical company in comparison with the mefenamic acid 500 mg sample of Pfizer in Turkey, after administration to 24 healthy human volunteers, two intervention administered to one group, in a cross-over manner. It is not blinded 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 500 mg mefenamic acid 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

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 as intervention 1: It includes oral consumption of mefenamic acid tablets 500 mg manufactured by Darou Darman Parmida Pharmaceutical Company in Iran and intervention 2: oral consumption of mefenamic acid tablets 500 mg manufactured by Pfizer Company in Turkey. 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: **IRCT20230222057495N10**

Registration date: **2023-11-11, 1402/08/20**

Registration timing: **prospective**

Last update: **2023-11-11, 1402/08/20**

Update count: **0**

Registration date

2023-11-11, 1402/08/20

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

2023-11-22, 1402/09/01

Expected recruitment end date

2024-11-21, 1403/09/01

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date
empty

Scientific title
Bioequivalence study of mefenamic acid 500 mg tablets of Darou Darman Parmida pharmaceutical company compared to mefenamic acid 500 mg of Pfizer in Turkey on healthy volunteers.

Public title
Bioequivalence study of mefenamic acid 500 mg tablets

Purpose
Other

Inclusion/Exclusion criteria
Inclusion criteria:
Healthy volunteers aged between 18 and 55 years. Body mass index less than 30 kg per square meter. All volunteers 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 drugs, alcohol or tobacco products 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: **0**

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
2023-10-17, 1402/07/25

Ethics committee reference number
IR.TUMS.TIPS.REC.1402.088

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 mefenamic acid

Timepoint
before starting to take the medicine and: 0.5, 1, 1.5, 2, 2.5, 3, 4, 5, 6, 8, 10 and 12 hours after taking the medicine

Method of measurement
Liquid chromatography - spectrophotometric detector

Secondary outcomes

empty

Intervention groups

1

Description
Intervention group 1: includes the oral administration of 500 mg of mefenamic acid from Darou Darman Parmida Pharmaceutical Company of Iran on 24 fasting healthy volunteers. 5 ml of blood at time intervals before taking the drug and: 0.5, 1, 1.5, 2, 2.5, 3, 4, 5, 6, 8, 10 and 12 hours after taking the drug, from Volunteers are taken. The cross-over study consists of two phases (oral consumption of one 500 mg mefenamic acid tablet per study and 2 times in total) with a one-week washout period (when the drug is completely removed from your blood). Mefenamic acid plasma concentration is determined by liquid chromatography-spectrophotometry method.

Category
Other

2

Description

Intervention group 2: includes the oral consumption of 500 mg of mefenamic acid from Pfizer in Turkey on 24 healthy fasting volunteers. 5 ml of blood at time intervals before taking the drug and: 0.5, 1, 1.5, 2, 2.5, 3, 4, 5, 6, 8, 10 and 12 hours after taking the drug, from Volunteers are taken. The cross-over study consists of two phases (oral consumption of one 500 mg mefenamic acid tablet per study and 2 times in total) with a one-week washout period (when the drug is completely removed from your blood). Mefenamic acid plasma concentration is determined by liquid chromatography-spectrophotometry 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

Darou Darman Parmida Pharmaceutical Company

Full name of responsible person

Maryam Motaghd

Street address

No. 128, Shahid Khandi St. (Palizi), North Sohrvardi St.

City

Tehran

Province

Tehran

Postal code

1554744371

Phone

+98 21 8396

Email

info@ddp.co.ir

Grant name

Grant code / Reference number

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

Yes

Title of funding source

Darou Darman Parmida 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

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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

Position

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Other areas of specialty/work

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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
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Street address
No. 419, Azadegan Squar, Imam Khomeini Boulevard
City
Mahdasht Karaj
Province
Alborz
Postal code

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