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 Motaghed

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

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Person responsible for scientific inquiries

Contact

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Nik Azma Pars Alborz laboratory

Full name of responsible person
Monireh Jalalipour

Position
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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
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Other areas of specialty/work
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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