

Clinical Trial Protocol

Iranian Registry of Clinical Trials

16 Jul 2026

Study of bioequivalence of 250 mg Mefenamic acid capsule in healthy volunteers after single dose oral administration

Protocol summary

Study aim

Determination of plasma concentration of 250 mg Mefenamic acid capsule generic product of Alborz Darou Company and 250 mg Mefenamic acid capsule reference Product of AA Pharma inc. Canada

Design

This study is a bioequivalence phase of clinical trial with control and cross over groups which is double-blinded and randomized and will be performed on 24 healthy subjects including 12 in control group and 12 in intervention group. For randomization, simple and restricted random allocation law is used.

Settings and conduct

This study is carried out at Shahid Beheshti School of Pharmacy, which has been the site of many similar studies. After receiving the drug orally, blood samples are taken from the volunteers at different times and the plasma concentration of the drug is measured by LC mass. In this double-blind study, volunteers, personnel and responsible physician is unaware for the type of drug and only the person responsible is aware of the type of drug. To ensure blinding, the drugs are removed from the box and both types are similar in appearance.

Participants/Inclusion and exclusion criteria

Inclusion criteria: Healthy volunteers aged 18 to 50 years
Exclusion criteria: History of liver, kidney and cardiovascular diseases that can affect drug clearance from body, History of taking any medication in the last two weeks, Creatinine above 2

Intervention groups

Intervention group: Oral intake of 250 mg Mefenamic acid capsule generic product of Alborz Darou Company with one dose and evaluation of plasma concentration up to 12 hours in the blood of healthy volunteers
Control group: Oral intake of 250 mg Mefenamic acid capsule reference product of AA Pharma inc. Canada with one dose and evaluation of plasma concentration up to 12 hours in the blood of healthy volunteers

Main outcome variables

Maximum plasma concentration of the drug

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20210201050197N6**

Registration date: **2022-09-03, 1401/06/12**

Registration timing: **prospective**

Last update: **2022-09-03, 1401/06/12**

Update count: **0**

Registration date

2022-09-03, 1401/06/12

Registrant information

Name

Azadeh Haeri

Name of organization / entity

Country

Iran (Islamic Republic of)

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a_haeri@sbmu.ac.ir

Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2022-09-06, 1401/06/15

Expected recruitment end date

2022-11-06, 1401/08/15

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Study of bioequivalence of 250 mg Mefenamic acid capsule in healthy volunteers after single dose oral administration

Public title

Bioequivalence of Mefenamic acid capsule

Purpose

Basic science

Inclusion/Exclusion criteria

Inclusion criteria:

Healthy volunteer Age_18-50 year

Exclusion criteria:

History of liver, kidney and cardiovascular diseases that can affect drug clearance from body History of taking any medication in the last two weeks Creatinine above 2

Age

From **18 years** old to **50 years** old

Gender

Both

Phase

Bioequivalence

Groups that have been masked

- Participant
- Care provider
- Outcome assessor
- Data analyser

Sample size

Target sample size: **24**

More than 1 sample in each individual

Number of samples in each individual: **2**

Each healthy volunteer receives 250 mg Mefenamic acid capsules made by Alborz Darou Company once and after two weeks, Mefenamic acid capsules 250 mg made by the AA Pharma Inc. company Canada or vice versa.

Randomization (investigator's opinion)

Randomized

Randomization description

In order to randomize in this study, simple and restricted random allocation rule will be used. This method represents a large block for the total sample size, meaning that the balance in the number of people assigned to each group will be achieved at the end. For this purpose, first, 24 candidates who meet the inclusion criteria will be selected. Then, 12 lotteries for the intervention group and 12 lotteries for the control group will be placed inside a lottery container. Then, randomly, each of these 24 individuals will take a lottery out of the container without replacement and deliver the lottery to the project officer and the allocation of the group to the individual will be determined (the person, physician and nurse responsible are not aware of the allocation of the group to the individual). In the second phase of the study, the person in the control group will be transferred to the intervention group and vice versa.

Blinding (investigator's opinion)

Double blinded

Blinding description

Volunteers and study physician are not aware of what

products they have received at any time. Since the drug is removed from its box and blister and give to the volunteers, they will not know the type of medicine. The new drug are similar to the reference drug in terms of color, smell, flavor and consistency and all the apparent properties so that participants do not know the type of drug.

Placebo

Not used

Assignment

Crossover

Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee

School of Pharmacy Nursing and Midwifery, Shahid Beheshti Medical University

Street address

No:2660, Faculty of Pharmacy, Shahid beheshti university of medical sciences, Nyayesh complex, Valiasr st.

City

Tehran

Province

Tehran

Postal code

1996835113

Approval date

2022-06-21, 1401/03/31

Ethics committee reference number

IR.SBMU.PHARMACY.REC.1401.066

Health conditions studied

1

Description of health condition studied

Determination of plasma concentration of Mefenamic acid 250 mg pharmaceutical product

ICD-10 code

ICD-10 code description

Primary outcomes

1

Description

Maximum plasma concentration of the drug

Timepoint

Before intervention and 0.5, 1, 1.5, 2, 2.5, 3, 4, 5, 6, 8, 10, 12 hours after intervention

Method of measurement

liquid chromatography-mass (LC-MS) device

Secondary outcomes

empty

Intervention groups

1

Description

Intervention group: In this group, 12 volunteers receive a 250 mg Mefenamic acid capsule made by Alborz Darou Company. Up to 12 hours, blood samples will be taken from the volunteers and plasma concentration of the drug will be measured by liquid chromatography. Each time, 5 cc blood samples are taken from volunteers. Then these 12 volunteers will enter the control group after one week.

Category

Other

2

Description

Control group: In this group, 12 volunteers receive 250 mg Mefenamic acid capsule made by AA Pharma inc. Canada company. Up to 12 hours, blood samples will be taken from the volunteers and plasma concentration of the drug will be measured by liquid chromatography. Each time, 5 cc blood samples are taken from volunteers. Then these 12 volunteers will enter the intervention group after one week.

Category

Other

Recruitment centers

1

Recruitment center

Name of recruitment center

School of Pharmacy, Shahid Beheshti University of Medical Sciences

Full name of responsible person

Azadeh Haeri

Street address

No:2660, Faculty of Pharmacy, Shahid beheshti university of medical sciences, Nyayesh complex, Valiasr st.

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Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Shahid Beheshti University of Medical Sciences

Full name of responsible person

Afshin Zarghi

Street address

5th Floor, Bldg No.2 SBMU, Arabi abbas Ave, Yaman Blvd, Chamran Blvd

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Grant name

Grant code / Reference number

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

No

Title of funding source

Shahid Beheshti University of Medical Sciences

Proportion provided by this source

100

Public or private sector

Public

Domestic or foreign origin

Domestic

Category of foreign source of funding

empty

Country of origin

Type of organization providing the funding

Academic

Person responsible for general inquiries

Contact

Name of organization / entity

Shahid Beheshti University of Medical Sciences

Full name of responsible person

Azadeh Haeri

Position

Associate professor

Latest degree

Ph.D.

Other areas of specialty/work

Medical Pharmacy

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Person responsible for scientific inquiries

Contact

Name of organization / entity

Shahid Beheshti University of Medical Sciences

Full name of responsible person

Azadeh Haeri

Position

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Person responsible for updating data

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Position

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Latest degree

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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

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