

Clinical Trial Protocol

Iranian Registry of Clinical Trials

21 Jul 2026

Randomized, single-dose, crossover comparative bioequivalence study of the Meloxicam 15 mg tablet produced by Daana pharmaceutical Co versus Mobic® (Boehringer Ingelheim company) in 24 healthy males under fasting conditions

Protocol summary

Study aim

To demonstrate bioequivalence of single dose test formulation of Daana Meloxicam 15 mg tablets versus Mobic® (Boehringer Ingelheim Co.)

Design

Single dose, randomized and crossover bioequivalence study of Meloxicam 15 mg tablets by Daana Co. with Mobic® (Boehringer Ingelheim Co.) in 24 healthy male in two groups under fasting condition.

Settings and conduct

Study place: Drug Applied Research Center affiliated to Tabriz University of Medical Science. Place for Blood and plasma sample analysis: Imam Reza Medical Research and Training Hospital. 24 healthy male volunteers will receive each of two test or reference Meloxicam 15 mg tablets in random sequence according to the randomization schedule. The interval between receiving the medicine (washout period) is 7 days. Blood samples of volunteers at 0 (before dosing), 1, 2, 2.5, 3, 3.5, 4, 4.5, 5, 6, 8, 10, 12, 24, 48 and 72 hour after dosing will be collected.

Participants/Inclusion and exclusion criteria

The weight limit for each volunteer is between 60 and 100 kg. They must be healthy in terms of liver, kidney, respiratory system, mental and other general health characteristics that will be assessed. Exclusion criteria: Known hypersensitivity or idiosyncratic reaction to Meloxicam or any ingredients. Subjects with BP $\leq$ 90/60 mm/Hg or BP $\geq$ 140/90 mm/Hg. Regular smoker who smokes more than ten cigarettes daily.

Intervention groups

Intervention group 1: In this group, volunteers are given a single oral dose of Meloxicam 15 mg tablets by Daana Co.. Intervention group 2: In this group, volunteers are given a single oral dose of Mobic® by Boehringer Ingelheim company. After the washout period, the

volunteers are placed in the opposite group. In fact, every single volunteers is used as control for himself.

Main outcome variables

Peak Plasma Concentration (Cmax); Area under the concentration-time curve (AUC).

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20200407046981N13**

Registration date: **2021-09-04, 1400/06/13**

Registration timing: **prospective**

Last update: **2021-09-04, 1400/06/13**

Update count: **0**

Registration date

2021-09-04, 1400/06/13

Registrant information

Name

Fatima Molavi

Name of organization / entity

Country

Iran (Islamic Republic of)

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Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2021-10-22, 1400/07/30

Expected recruitment end date

2022-01-20, 1400/10/30

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Randomized, single-dose, crossover comparative bioequivalence study of the Meloxicam 15 mg tablet produced by Daana pharmaceutical Co versus Mobic® (Boehringer Ingelheim company) in 24 healthy males under fasting conditions

Public title

Study of absorption and elimination rate of Meloxicam 15 mg tablets in comparison with standard tablets of Meloxicam (Mobic®).

Purpose

Treatment

Inclusion/Exclusion criteria**Inclusion criteria:**

The weight limit for each volunteer is between 60 and 100 kg. All volunteers must be non-smokers. They must be healthy in terms of liver, kidney, respiratory system, mental and other general health characteristics that will be assessed.

Exclusion criteria:

Known hypersensitivity or idiosyncratic reaction to Meloxicam or any ingredients. Subjects with BP $\leq$ 90/60 mm/Hg or BP $\geq$ 140/90 mm/Hg. Regular smoker who smokes more than ten cigarettes daily. Taking any medicine during two week before dosing.

Age

From **18 years** old to **60 years** old

Gender

Male

Phase

Bioequivalence

Groups that have been masked

No information

Sample size

Target sample size: **24**

Randomization (investigator's opinion)

Randomized

Randomization description

First, a table of random numbers from 1 to 24 is created. The table numbers are assigned to individuals in the order in which the candidates enter the list on the day of the experiment, and the candidates in two groups with numbers 1-12 and numbers 13-24 will receive reference and test medicine, respectively.

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**

Ethics committee of Tabriz University of Medical Science

Street address

Third floor, central building No. 2, Golgasht street, Tabriz University of Medical Science, Tabriz, Iran

City

Tabriz

Province

East Azarbaijan

Postal code

5166614766

Approval date

2021-08-02, 1400/05/11

Ethics committee reference number

IR.TBZMED.REC.1400.473

Health conditions studied**1****Description of health condition studied**

Bioequivalence study

ICD-10 code**ICD-10 code description****Primary outcomes****1****Description**

Peak Plasma Concentration (Cmax)

Timepoint

At 0 (before dosing), 1, 2, 2.5, 3, 3.5, 4, 4.5, 5, 6, 8, 10, 12, 24, 48 and 72 hour after dosing

Method of measurement

High-performance liquid chromatography—mass spectrometry (HPLC-MS)

Secondary outcomes**1****Description**

AUC (Area Under the Concentration-Time Curve)

Timepoint

During 2 months after intervention

Method of measurement

Using non-compartmental model of Win-Nonlin Professional software version 3.2.A (Pharsight Corporation, USA) or SPSS

Intervention groups

1

Description

Intervention group 1: In this group, volunteers are given a single oral dose of Meloxicom 15 mg tablets, produced by Daana Co. (Domestic). After the washout period, the volunteers are placed in the Intervention group 2. In fact, every single volunteers is used as control for himself.

Category

Treatment - Drugs

2

Description

Intervention group 2: In this group, volunteers are given a single oral dose of Meloxicom 15 mg tablets (Mobic), produced by Boehringer Ingelheim Company (Brand). After the washout period, the volunteers are placed in the Intervention group 1. In fact, every single volunteers is used as control for himself.

Category

Treatment - Drugs

Recruitment centers

1

Recruitment center

Name of recruitment center

Drug Applied Research Center

Full name of responsible person

Dr Hamed Hamishehkar

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Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Daana pharmaceutical company

Full name of responsible person

Ahmad Kharazi

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Grant name

Grant code / Reference number

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

Yes

Title of funding source

Daana 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

Tabriz University of Medical Sciences

Full name of responsible person

Hamed Hamishehkar

Position

Professor

Latest degree

Ph.D.

Other areas of specialty/work

Pharmaceutics

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Person responsible for scientific inquiries

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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)

No - There is not a plan to make this available

Justification/reason for indecision/not sharing IPD

There is no further information

Study Protocol

Undecided - It is not yet known if there will be a plan to
make this available

Statistical Analysis Plan

No - There is not 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

Not applicable

Data Dictionary

No - There is not a plan to make this available