

Clinical Trial Protocol

Iranian Registry of Clinical Trials

09 Jun 2026

Comparative bioequivalence study of Mesalazine 500 mg ER Capsule of ActoverCo. and PENTASA® of Ferring as reference in 24 healthy male under fasting condition

Protocol summary

Study aim

This study will be performed to compare the pharmacokinetics and in vivo parameters of Mesalazine 500 mg ER Capsule formulation as a test product with Mesalazine 500 mg ER Capsule formulation as a reference product and to evaluate the bioequivalence of these two formulations.

Design

Non-blinded, randomized, crossover in vivo bioequivalence study on 24 healthy males under fasting conditions. Block randomization for a treatment sequence of Test/Reference or Reference/Test is used.

Settings and conduct

During each study period, volunteers will receive a single dose intervention (1 or 2) in the Farabi Clinic (Eslamshahr, Tehran). In total, 17 blood samples will be collected during 72 hours post intervention. A 14-day washout interval will separate the study periods.

Participants/Inclusion and exclusion criteria

Inclusion Criteria: Healthy subjects (male) between 20-45 years of age and Body Mass Index (BMI) within 15% of normal range according to the accepted normal values between 18.5 and 30 (inclusive), calculated as kg/m². Exclusion Criteria: Subjects with known allergy to the products tested or NSAIDs; Subjects with clinically significant abnormal findings during screening, medical history, clinical examination and laboratory evaluations; Significant clinical illness within 3 weeks prior to screening.

Intervention groups

Intervention group 1: Mesalazine 500 mg ER Capsule, produced by Karen. is the test product. In each period, 12 of 24 subjects will be given a single oral dose of this product. Intervention group 2: Mesalazine 500 mg ER Capsule (PENTASA®), produced by Ferring is the reference product. In each period, 12 of 24 subjects will be given a single oral dose of this product.

Main outcome variables

Peak Plasma Concentration

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20180620040164N49**

Registration date: **2023-09-11, 1402/06/20**

Registration timing: **registered_while_recruiting**

Last update: **2023-09-11, 1402/06/20**

Update count: **0**

Registration date

2023-09-11, 1402/06/20

Registrant information

Name

Behzad Montaha Sangari

Name of organization / entity

Noor research and educational institute (Tavan)

Country

Iran (Islamic Republic of)

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Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2023-09-06, 1402/06/15

Expected recruitment end date

2023-09-20, 1402/06/29

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Comparative bioequivalence study of Mesalazine 500 mg ER Capsule of ActoverCo. and PENTASA® of Ferring as reference in 24 healthy male under fasting condition

Public title

Comparative in vivo evaluation of 2 Mesalazine 500 mg ER Capsule and PENTASA® 500 mg ER Tablet formulations.

Purpose

Treatment

Inclusion/Exclusion criteria**Inclusion criteria:**

Healthy subjects (male) between 20 – 45 years of age. Body Mass Index (BMI) within 15% of normal range according to the accepted normal values between 18.5 and 30 (inclusive), calculated as kg/m². Subjects with normal vital signs. Subjects who agree with patient consent form.

Exclusion criteria:

Subjects with clinically significant abnormal findings during screening, medical history, clinical examination and laboratory evaluations. Subjects with known allergy to the products tested or NSAIDs. Significant clinical illness within 3 weeks prior to screening. History of GI surgery or any other surgery within the past 3 months. History of any significant disease that jeopardize safety of the subject or validity of test results. History of consumption of prescribed medication since last 14 days or OTC medication since last 07 days before beginning of the study. Smoking more than 10 cigarettes per day and could not tolerate cigarette cessation during each clinical period. History of alcohol or drug abuse. Heavy drinker of caffeine, grapefruit juice or caffeinated drinks or who are on special diet (such as vegetarians) or do exertional physical activity; A history of difficulty with donating blood or donation of more than 500 ml blood within 7 days prior to the start of the study

Age

From **20 years** old to **45 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

The randomization schedule will be generated with <https://www.sealedenvelope.com/simple-randomiser/v1/lists>. A 2*2 block randomization list is created. We have 12 blocks and within each two volunteer numbers (allocated after screening) for all 24 volunteers. According to this list, a treatment sequence of

Test/Reference or Reference/Test will be given to each volunteer.

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, School of Pharmacy, Nursing & Midwifery; Shahid Beheshti University of medical science

Street address

Niayesh Highway, Valiasr Ave, Tehran, Iran

City

Tehran

Province

Tehran

Postal code

1996835113

Approval date

2020-03-02, 1398/12/12

Ethics committee reference number

IR.SBMU.PHARMACY.REC.1398.305

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

Ulcerative colitis

ICD-10 code

K51

ICD-10 code description

Ulcerative colitis

Primary outcomes**1****Description**

Peak Plasma Concentration (C_{max})

Timepoint

14 blood samples will be withdrawn pre-dose and at 1, 2, 3, 4, 5, 6, 7, 8, 10, 12, 24, 48 and 72 hours after intervention.

Method of measurement

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

Secondary outcomes

1

Description

AUC (Area Under the Concentration-Time Curve)

Timepoint

14 blood samples will be withdrawn pre-dose and at 1, 2, 3, 4, 5, 6, 7, 8, 10, 12, 24, 48 and 72 hours after intervention.

Method of measurement

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

Intervention groups

1

Description

Intervention group 1: Mesalazine 500 mg ER Capsule , produced by Karen. is the test product. In each period, 12 of 24 subjects will be given single oral dose of this product. After 14-day wash-out period the intervention 2 will be given to these subjects.

Category

Treatment - Drugs

2

Description

Intervention group 2: Mesalazine 500 mg ER Capsule (PENTASA®), produced by Ferring is the reference product. In each period, 12 of 24 subjects will be given single oral dose of this product. After 14-day wash-out period the intervention 1 will be given to these subjects.

Category

Treatment - Drugs

Recruitment centers

1

Recruitment center

Name of recruitment center

Hakim Farabi Clinic

Full name of responsible person

Ebrahim Siahpoosh

Street address

No. 57, Shemshad alley, in front of Sallor town

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Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Actover Pharmaceutical Co.

Full name of responsible person

Dr. Ramin Daneshmir

Street address

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Tehran

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1446863914

Phone

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Email

info@actoverco.com

Grant name

Grant code / Reference number

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

Yes

Title of funding source

Actover Pharmaceutical Co.

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

Noor Research & Development Institute

Full name of responsible person

Ali Aghaei

Position

Master

Latest degree

Master

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
No - There is not 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
No - There is not a plan to make this available
Data Dictionary
No - There is not a plan to make this available