Clinical Trial Protocol
Iranian Registry of Clinical Trials

17 Sep 2026

Comparative bioequivalence study of Mesalazine 500 mg ER Capsule of Karen. 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 invivo parameters of Mesalazine 500 mg ER Capsule formulation as a test product with Mesalazine 500 mg ER Tablet 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 Tablet (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: **IRCT20180620040164N46**
Registration date: **2023-05-31, 1402/03/10**
Registration timing: **prospective**

Last update: **2023-05-31, 1402/03/10**
Update count: **0**

Registration date

2023-05-31, 1402/03/10

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

2023-06-23, 1402/04/02

Expected recruitment end date

2023-07-07, 1402/04/16

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 Karen. 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 Mesalazine 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
2023-01-24, 1401/11/04
Ethics committee reference number
IR.SBMU.PHARMACY.REC.1401.236

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 (Cmax)
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 group1: 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 Tablet (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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Tehran
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4635314588
Phone
+98 21 9253 5647
Email
partochem@gmail.com

Sponsors / Funding sources

1

Sponsor
Name of organization / entity
Karen Pharma and Food Supplement Co.
Full name of responsible person
Zahra Mortazavi
Street address
No: 3, Western Nahid st. Africa Blvd.
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Tehran
Province
Tehran
Postal code
+98 21 2620 4283
Phone
+98 21 2620 4283
Email
info@karenpharma.com
Grant name
Grant code / Reference number
Is the source of funding the same sponsor organization/entity?
Yes
Title of funding source
Karen Pharma and Food Supplement 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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Person responsible for updating data

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Ali aghaei
Position
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Latest degree
Master
Other areas of specialty/work
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No-Avari Sharif station, North Habibollah Street, Hosseini Square, Teymoury Street, Tarasht
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1459926609
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Email
partochem@gmail.com

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