

# Clinical Trial Protocol

## Iranian Registry of Clinical Trials

09 Jun 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 in vivo 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/m<sup>2</sup>.  
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)

##### Phone

+98 21 6600 7026

##### Email address

info@tavaninstitute.ir

##### 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/m<sup>2</sup>  
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 (C<sub>max</sub>)

**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

##### City

Tehran

##### Province

Tehran

##### Postal code

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.

##### City

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

Pharmacy

##### Street address

Sharif innovation station, North Habibollah Street, Hosseini Square, Teymoury Street, Tarasht.

##### City

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##### Province

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## Person responsible for scientific inquiries

### Contact

**Name of organization / entity**  
Tavan Institute  
**Full name of responsible person**  
Seyed Mohsen Foroutan  
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Principal investigator  
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Ph.D.  
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Medical Pharmacy  
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## Person responsible for updating data

### Contact

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1459926609  
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+98 21 6600 4027  
**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