

Clinical Trial Protocol

Iranian Registry of Clinical Trials

25 Jun 2026

In- Vivo Bioequivalence study of Mesalazine SR. granules 2 g Kooshan Pharmed Co. (Mezasa® 2g SR. granules) with brand drugs (PENTASA® 2g SR. granules (Ferring Pharmaceuticals Co, Gremany) in Iranian healthy volunteers.

Protocol summary

Study aim

In- Vivo Bioequivalence study of Mesalazine SR granules 2 g Kooshan Pharmed Co. (Mezasa® 2g SR. granules) with brand drugs (PENTASA® 2g SR. granules (Ferring Pharmaceuticals Co, Gremany) in Iranian healthy volunteers.

Design

Single dose, randomized, two sequences, two period crossover with a washout period.

Settings and conduct

This study will be conducted in single-dose, cross-over, and fasting, and on two sets of healthy volunteers. The study will be conducted in two periods of 72 hours. The interval between these two periods, which is called the wash-out time, is determined by the half-life of the drug plasma, which according to scientific sources should be at least 5 to 7 half-life of the drug in the case of the drug under study. The plan will take a week to clean up the drug, given the biological half-life of the drugs in the drug form. In the first round, candidates are divided into two groups, and the first group receives a test tablet and the second group receives similar tablets. Blood samples will be taken by the volunteer by the technician immediately after taking the drug, and the preparation steps of the samples, including plasma separation and drug extraction, are performed to analyze the amount of drug on them.

Participants/Inclusion and exclusion criteria

24 participants will be selected from non-smoking, not pregnant people with no history of heart, kidney, and liver disease or dysfunctions with both sexes (male&female). The ages and BMIs of the participants should be in the range of 18-60 and 18-28 respectively

Intervention groups

Single dose Mesalazine SR granules 2 g Kooshan Pharmed Company with brand drugs PENTASA granules

Ferring Pharmaceuticals Co, Gremany)

Main outcome variables

Determination of blood drug concentration

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20200105046010N40**

Registration date: **2021-09-19, 1400/06/28**

Registration timing: **registered_while_recruiting**

Last update: **2021-09-19, 1400/06/28**

Update count: **0**

Registration date

2021-09-19, 1400/06/28

Registrant information

Name

Javad Shokri

Name of organization / entity

Country

Iran (Islamic Republic of)

Phone

+98 41 3661 4125

Email address

shokri.j@gmail.com

Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2021-09-01, 1400/06/10

Expected recruitment end date

2022-03-16, 1400/12/25

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

In- Vivo Bioequivalence study of Mesalazine SR. granules 2 g Kooshan Pharmed Co. (Mezasa® 2g SR. granules) with brand drugs (PENTASA® 2g SR. granules (Ferring Pharmaceuticals Co, Germany) in Iranian healthy volunteers.

Public title

In-vivo Bioequivalence study of Mezasa granules with brand drugs (PENTASA Ferring Pharmaceuticals Co, Germany)

Purpose

Treatment

Inclusion/Exclusion criteria**Inclusion criteria:**

General health Body mass index(18-28) Informed consent Age(18-60)

Exclusion criteria:

Smoking A history of cardiovascular disease A history of liver & kidney disease Pregnancy Alcohol & Drug addiction Hypersensitivity to the drug

Age

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

Gender

Both

Phase

Bioequivalence

Groups that have been masked

- Participant

Sample size

Target sample size: **24**

Randomization (investigator's opinion)

Randomized

Randomization description

For this purpose, first determine a total sample size (24 people), then write the names of the people on paper, and after folding in aluminum foil, pour it into a glass, and then randomly remove the papers and open the first 12 people in group A and The rest are selected as group B.

Blinding (investigator's opinion)

Single blinded

Blinding description

Iranian Mesalazine granules and Mesalazine brand are removed from their packaging by the executor and placed in similar and coded cans. Volunteers will not be informed about receiving the brand or test medications

Placebo

Not used

Assignment

Crossover

Other design features**Secondary Ids**

empty

Ethics committees**1****Ethics committee****Name of ethics committee**

Ethics Committee, Tabriz University of Medical Sciences

Street address

Third floor of TUMS (Tabriz University of Medical Sciences) central building, Dneshgah St. Tabriz, Iran

City

Tabriz

Province

East Azarbaijan

Postal code

5166614766

Approval date

2021-03-01, 1399/12/11

Ethics committee reference number

IR.TBZMED.REC.1399.1156

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

Bio equivalence test

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

Determination of blood drug concentration.

Timepoint

Sampling times in this study will be 0, 1, 2, 2:30, 3, 3:20, 3:40, 4, 4:20, 4: 40, 5, 6, 8, 10, 12, 24, 48, 72 hours After prescribing the tablet.

Method of measurement

High Performance Liquid Chromatography with tandem mass spectroscopy detector

Secondary outcomes

empty

Intervention groups**1****Description**

Intervention group: will receive one test granules tablet (Mezasa® 2g SR granules Kooshan Pharmed Co). Blood samples will be taken from the volunteers for 72 hours at the mentioned times after drug administration and the

concentration of Mesalazine in blood samples will be measured by liquid chromatography with mass spectroscopy detector.

Category

Treatment - Devices

2**Description**

Control group: will receive one test granules table (PENTASA® 2g SR granules Ferring Pharmaceuticals Co, Germany). Blood samples will be taken from the volunteers for 72 hours at the mentioned times after drug administration and the concentration of Mesalazine in blood samples will be measured by liquid chromatography with mass spectroscopy detector.

Category

Treatment - Other

Recruitment centers**1****Recruitment center****Name of recruitment center**

Simin Baspar Teyf Gostar Company

Full name of responsible person

Javad Shokri

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No.48, Ferdos Street

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Sponsors / Funding sources**1****Sponsor****Name of organization / entity**

Koushan Pharmed Pharmaceutical Company

Full name of responsible person

Delaram Amini

Street address

No.15, Padidar Alley, Africa Blvd

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Phone

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Fax

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Email

CRM@koushanpharmed.com

Web page address

http://www.koushanpharmed.com

Grant name**Grant code / Reference number****Is the source of funding the same sponsor organization/entity?**

Yes

Title of funding source

Koushan Pharmed 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**

Persons

Person responsible for general inquiries**Contact****Name of organization / entity**

Tabriz University of Medical Sciences

Full name of responsible person

Javad Shokri

Position

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**

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Person responsible for updating data**Contact****Name of organization / entity**

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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

These data are as secure between researcher and related industries

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

Yes - There is a plan to make this available

Title and more details about the data/document

Only protocol and methods of study are sharable

When the data will become available and for how long

Only protocol and methods of study are shareable.

To whom data/document is available

Pharmaceutical and medical sciences researchers

Under which criteria data/document could be used

Projects information's for any publications is not allowed.

From where data/document is obtainable

By email to the project manager (shokri.j@gmail.com)

What processes are involved for a request to access data/document

This information is confidential and is at the disposal of the project sponsor. Upon request, the information will be provided to the applicant by the contractor's email after the

Comments