Clinical Trial Protocol
Iranian Registry of Clinical Trials

24 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, Gremany) in Iranian healthy volunteers.

Public title
In-vivo Bioequivalence study of Mezasa granules with brand drugs (PENTASA Ferring Pharmaceuticals Co, Gremany)
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, Gremany). 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

Street address

No.48, Ferdos Street

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5167874434

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+98 41 3384 2724

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Shokri.j@gmail.com

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

City

Tehran

Province

Tehran

Postal code

1518943814

Phone

+98 21 8819 7148

Fax

+98 21 8819 7153

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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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 date 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