Clinical Trial Protocol
Iranian Registry of Clinical Trials

16 Sep 2026

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

Protocol summary

Study aim

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

Design

In-vivo bioequivalence study of Mesalazine SR granules 2 g Teb Mofid Nikan Pharma. in compared with reference drug (Ferring Pharmaceuticals Co, Gremany). The single blind, Cross-over, two period, two sequences (Intervention and control) and randomized study with one week wash-out period.

Settings and conduct

This study is carried out in Simin Baspar Tayf-Gostar Company, Tabriz, Iran. The study population is 24 healthy Iranian volunteers.This study is a single blind study and by taking out the drugs from the existing packaging, the volunteers will not know the time of receiving the test drug and the brand. This study is a cross over study that is performed in two time periods of 72 hours with a two-week wash-out period.

Participants/Inclusion and exclusion criteria

Inclusion criteria: Age between 18-55 years, body mass index (BMI) in the range of 18-28. Exclusion criteria: History of heart, kidney and liver disease, Pregnancy, Drug addiction, Smoking

Intervention groups

Single dose Mesalazine SR granules 2 g Teb Mofid Nikan Pharma. Control group: brand drugs (Ferring Pharmaceuticals Co, Gremany)

Main outcome variables

Plasma drug concentration

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20200105046010N50**
Registration date: **2021-12-25, 1400/10/04**
Registration timing: **registered_while_recruiting**

Last update: **2021-12-25, 1400/10/04**
Update count: **0**

Registration date

2021-12-25, 1400/10/04

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

2021-12-12, 1400/09/21

Expected recruitment end date

2022-06-11, 1401/03/21

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, Teb Mofid Nikan Pharmed Co. (MODACOLIT® 2 g SR Granules) with brand drugs (PENTASA® 2g SR. granules) Ferring Pharmaceuticals Co, Germany in Iranian healthy volunteers.

Public title

In-vivo Bioequivalence Test of MODACOLIT SR Granules with brand drug (Ferring Pharmaceuticals Co, Gremany)

Purpose

Treatment

Inclusion/Exclusion criteria

Inclusion criteria:

General health Body mass index between18-28 Informed consent Being at the age of 18-55 years old

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 **55 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, A 24- persons group will be selected and divided to two 12-persons groups randomly. The names of all volunteers will be written on paper pieces and wrapped in aluminum foils. The first 12 papers will randomly be withdrawn from bottle will be selected as group A and others will be categorized in group B.

Blinding (investigator's opinion)

Single blinded

Blinding description

Candidates are not aware of receiving the test drug or brand one. In a one-blind study, information that could distort the test result is hidden from the candidates, but the person in charge of the test is aware of it. Test and Brand drugs 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 drug.

Placebo

Not used

Assignment

Crossover

Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee

Ethics Committee of Tabriz University of Medical Sciences

Street address

Third floor; Central building; Tabriz University of Medical Sciences; Dneshgah St.

City

Tabriz

Province

East Azarbaijan

Postal code

5166614766

Approval date

2021-11-15, 1400/08/24

Ethics committee reference number

IR.TBZMED.REC.1400.737

Health conditions studied

1

Description of health condition studied

Bio equivalence test

ICD-10 code

ICD-10 code description

Primary outcomes

1

Description

Plasma drug concentration

Timepoint

Sampling times in this study will be 0, 1, 2, 3, 4, 6, 7, 8, 9, 10, 10:30, 11, 12, 24, 36, 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: One test tablet (Mesalazine SR granules 2 g ، produced by Teb Mofid Nikan Pharma.) will be received. Blood samples will be taken for 72 hours at the mentioned times after drug administration and the concentration of the drug in Plasma samples will be measured by liquid chromatography with mass spectroscopy detector

Category

Treatment - Other

2

Description
Control group: One Reference granule (PENTASA® 2g SR. granules, Ferring Pharmaceuticals Co, Gremany) will be received. Blood samples will be taken for 72 hours at the mentioned times after drug administration and the concentration of Mesalazine in plasma samples will be measured by liquid chromatography with mass spectroscopy detector. After one week wash out period, the test drug taken by other sequence of volunteers.

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 square

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Tabriz

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East Azarbaijan

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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
Teb Mofid Nikan Pharmaceutical Co.

Full name of responsible person
Mohammad Reza Zargarzadeh

Street address
Tehran Shahid Beheshti Street Ahmad Qusayr Street, Pazhouheshgah(2) alley, fifth floor

City
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Province
Tehran

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3361658369

Phone
+98 21 8817 5119

Fax
+98 26 4422 8116

Email
info@mofidpharma.com

Grant name

Grant code / Reference number

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

Title of funding source
Teb Mofid Nikan 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
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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Full name of responsible person
Javad Shokri

Position
Professor

Latest degree
Ph.D.

Other areas of specialty/work
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Person responsible for updating data

Contact

Name of organization / entity

Simin Baspar Teyf Gostar Company

Full name of responsible person

Dariush Omidar

Position

Lab. Manager

Latest degree

Master

Other areas of specialty/work

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City

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Dariush.omidfar@gmail.com

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

All information and data of the study will remain secured based on the agreement established between researcher and drug producer.

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

The access to data will be possible after finishing of project (almost 6 months after receiving of IRCT Code).

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

These information are confidential and be under disposal of the project's contractor. Upon request, the information will be accessed to the applicant by the Executor's email after receiving contractor's consent.

Comments