Clinical Trial Protocol
Iranian Registry of Clinical Trials

17 Sep 2026

Randomized, single-dose, crossover comparative bioequivalence study of the Domperidone suspension 1 mg/ml (200 mL) produced by Razan pharmed Iranian pharmaceutical Co versus Motilium® (Janssen company) in 24 healthy males under fasting conditions

Protocol summary

Study aim

To demonstrate bioequivalence of single dose test formulation of Razan Pharmed Iranian Co. Domperidone suspension 1 mg/mL versus Motilium (Janssen Company)

Design

Single dose, randomized and crossover bioequivalence study of Domperidone suspension, produced by Razan Pharmed Iranian Co. with Motilium in 24 healthy male in two groups under fasting condition.Data will be analyzed with Excel and SPSS software.

Settings and conduct

Study place: Drug Applied Research Center affiliated to Tabriz University of Medical Science. Place for Blood and plasma sample analysis: Imam Reza Medical Research and Training Hospital. The 24 healthy male volunteers will receive 20 cc of the two 1mg/ml domperidone suspensions (test or reference) based on a randomized program with 7-day drug clearance period, After this period, people will consume alternative products. Blood samples of all volunteers before receiving the drug and up to 48 hours, after the specified times: at 0 (before prescribing the drug), 0.25, 0.5, 0.75, 1, 1.5, 2, 2.5, 3, 4, 6 , 8, 12, 24, 36 and 48 hours are collected for pharmacokinetic studies.

Participants/Inclusion and exclusion criteria

Inclusion criteria: Healthy male subjects in the age range of 18-60 years and BMI (Body Mass Index) of 18.5-30. Exclusion criteria: subjects with a history of disease and unusual measures in blood and clinical examination and heavy smokers.

Intervention groups

Intervention group 1 (Test): Domperidone suspension 1 mg/mL, produced by Razan Pharmed Iranian Co. is the test product. In each period, 12 of 24 subjects will be given single oral dose of this product.Intervention group 2 (Reference): Domperidone suspension(produced by Janssen) is the reference product. In each period, 12 of 24 subjects will be given single oral dose of this product.

Main outcome variables

Peak Plasma Concentration (Cmax); Area under the concentration-time curve (AUC).

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20200407046981N10**
Registration date: **2021-06-22, 1400/04/01**
Registration timing: **prospective**

Last update: **2021-06-22, 1400/04/01**
Update count: **0**

Registration date

2021-06-22, 1400/04/01

Registrant information

Name

Fatima Molavi

Name of organization / entity

Country

Iran (Islamic Republic of)

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Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2021-07-06, 1400/04/15

Expected recruitment end date
2021-09-06, 1400/06/15
Actual recruitment start date
empty
Actual recruitment end date
empty
Trial completion date
empty

Scientific title
Randomized, single-dose, crossover comparative bioequivalence study of the Domperidone suspension 1 mg/ml (200 mL) produced by Razan pharmed Iranian pharmaceutical Co versus Motilium® (Janssen company) in 24 healthy males under fasting conditions

Public title
Bioequivalence of a New Generic Formulation of Domperidone 1 mg/ml (200 mL) suspension produced by Razan pharmed Iranian pharmaceutical Co versus Motilium® after single dose administration to healthy volunteers
Purpose
Health service research
Inclusion/Exclusion criteria
Inclusion criteria:
The weight limit for each volunteer is between 60 and 100 kg. Only non-smokers are allowed to participate. They must be healthy in terms of liver, kidney, respiratory system, mental and other general health characteristics that will be assessed.
Exclusion criteria:
Known hypersensitivity or idiosyncratic reaction to Domperidone or any ingredients. Subjects with BP ≤ 90/60 mm/Hg or BP ≥ 140/90 mm/Hg. Regular smoker who smokes more than ten cigarettes daily. Taking any medicine during two week before dosing.
Age
From **18 years** old to **60 years** old
Gender
Male

Phase
Bioequivalence
Groups that have been masked
No information
Sample size
Target sample size: **24**
More than 1 sample in each individual
Number of samples in each individual: **2**
Candidates of the sequences must take one of the Iranian or brand drugs, if the first sequence of the volunteers received the domestic drug after the washout period, they must receive the brand drug. In fact,every single volunteers is used as control for himself.
Randomization (investigator's opinion)
Randomized
Randomization description
Individuals will be recruited with advertising. 24 volunteers will be allocated to two sequences randomly by lottery method.The number was allocated according to their entrance to volunteers' list in screening day.
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 of Tabriz University of Medical Science
Street address
Third floor, central building No. 2, Golgasht street, Tabriz University of Medical Science, Tabriz, Iran
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Tabriz
Province
East Azarbaijan
Postal code
5166614766
Approval date
2021-05-31, 1400/03/10
Ethics committee reference number
IR.TBZMED.REC.1400.251

Health conditions studied

1

Description of health condition studied
In this study, the disease is not examined. The subject of the study is the bioequivalence study of the Domperidone suspension of test and reference in healthy volunteers.
ICD-10 code
ICD-10 code description

Primary outcomes

1

Description
Peak Plasma Concentration (Cmax)
Timepoint
At 0 (before dosing), 0.25, 0.5, 0.75, 1, 1.5, 2, 2.5, 3, 4, 6, 8, 12, 24, 36 and48 hour after dosing
Method of measurement
High-performance liquid chromatography—mass spectrometry (HPLC-MS)

Secondary outcomes

1

Description
AUC (Area Under the Concentration-Time Curve)
Timepoint
During 2 months after intervention
Method of measurement
Using non-compartmental model of Win-Nonlin Professional software version 3.2.A (Pharsight Corporation, USA) or SPSS

Intervention groups

1

Description
Intervention group (Test): Domperidone Suspension 1 mg/mL produced by Razan Pharmed Iranian is the test product. In each period, 12 of 24 subjects will be given 20 cc of single oral dose of this product. In the second period, after washout, this group (test) will be in the reference group and will use brand drug (Motilium).
Category
Treatment - Drugs

2

Description
Intervention group (Reference): Domperidone Suspension 1 mg/mL (Motilium), produced by Janssen Company is the test product. In each period, 12 of 24 subjects will be given 20 cc of single oral dose of this product. In the second period, after washout, this group (Reference) will be in the test group and will use domestic Domperidone Suspension.
Category
Treatment - Drugs

Recruitment centers

1

Recruitment center
Name of recruitment center
Drug Applied Research Center
Full name of responsible person
Dr Hamed Hamishehkar
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Sponsors / Funding sources

1

Sponsor
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Full name of responsible person
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Grant name
شرکت داروسازی رازان فارمد ایرانیان
Grant code / Reference number
Is the source of funding the same sponsor organization/entity?
Yes
Title of funding source
شرکت داروسازی رازان فارمد ایرانیان
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
Tabriz University of Medical Sciences
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Position
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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
Undecided - It is not yet known if there will be 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